

US3552191 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:13:34

All time stamps listed in this document are displayed in GMT

US3552191

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 18:11:07

Generated On: 10 Jun 2021 08:13:34

Participant ID

US3552191

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

US3552191

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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 18:11:23

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
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 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	ROSACEA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	BREAST CANCER
Start date (dd MMM yyyy)	UN JAN 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 JAN 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	MEDICATION ALLERGY: TOLECTIN
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
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 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	HERNIATED DISC
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
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 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	LEFT HEEL ACHILLES TENDONITIS
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 (15)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	SEASONAL ALLERGIES
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 (16)

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Condition	OBSTRUCTIVE SLEEP APNEA
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: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:00
Height (xxx.x)	65 in
Weight (xxx.x)	171.2 lb
BMI (xxx.x)	28.54874 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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 18:11:23

Generated On: 10 Jun 2021 08:13:34

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*) UN UNK 2003

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 18:11:23

Generated On: 10 Jun 2021 08:13:34

BABYSITS GRANDCHILDREN
(AGES 9, 5, AND TWO ARE 3
YEARS OLD) 1 - 3 TIMES A
WEEK, GROCERY SHOPPING
TWICE A WEEK, ATTENDS
CHURCH SERVICES WEEKLY,
WEARS MASK WHEN OUT.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

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 18:11:24

Generated On: 10 Jun 2021 08:13:34

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

What was the participant's randomization number? 188537

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 18:11:24

Generated On: 10 Jun 2021 08:13:34

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 18:11:24

Generated On: 10 Jun 2021 08:13:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 13:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 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 18:11:24

Generated On: 10 Jun 2021 08:13:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

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) 15:20 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 15:20

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	14:38 (24 HR)
Collection date and time (derived)	26 AUG 2020 14:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:45	26 AUG 2020 14:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

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 08:13:34

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 15:59

PC Open Date & Time

26 AUG 2020 15:40

PC Close Date & Time

26 AUG 2020 18:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐
No ☒

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

PC Time Stamp	27 AUG 2020 11:04
PC Open Date & Time	26 AUG 2020 19:05
PC Close Date & Time	27 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 20:19

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

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

99.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:21

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 19:24

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 19:13

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 19:56

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 19:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 15:59

PC Open Date & Time

26 AUG 2020 15:40

PC Close Date & Time

26 AUG 2020 18:10

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 11:05

PC Open Date & Time

26 AUG 2020 19:05

PC Close Date & Time

27 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 20:19

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:21

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 19:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 19:13

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 19:57

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 19:39

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 16:00
PC Open Date & Time	26 AUG 2020 15:40
PC Close Date & Time	26 AUG 2020 18:10

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 11:06
PC Open Date & Time	26 AUG 2020 19:05
PC Close Date & Time	27 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:20
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:22
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:25
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

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 ☒

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:14
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:57
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:39
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:04
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3552191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

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.

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 23 SEP 2020

What was the treatment time? (00:00-23:59) 09:34 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 09:34

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

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	09:12 (24 HR)
Collection date and time (derived)	23 SEP 2020 09:12

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:15	23 SEP 2020 09:15
Nasopharyngeal Swab 2	No		

US3552191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 10:03

PC Open Date & Time

23 SEP 2020 09:54

PC Close Date & Time

23 SEP 2020 12:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp	23 SEP 2020 18:25
PC Open Date & Time	23 SEP 2020 13:19
PC Close Date & Time	24 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

101.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 19:43

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 18:45

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

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):

PC Time Stamp

28 SEP 2020 20:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 22:11

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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

23 SEP 2020 10:03

PC Open Date & Time

23 SEP 2020 09:54

PC Close Date & Time

23 SEP 2020 12:24

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 18:25

PC Open Date & Time

23 SEP 2020 13:19

PC Close Date & Time

24 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 18:41

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 18:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input type="radio"/>
Please select one response below	Does not interfere with activity <input checked="" type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	Does not interfere with activity <input type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	26 SEP 2020 19:44
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 18:46

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 20:14

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 22:12

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 10:04
PC Open Date & Time	23 SEP 2020 09:54
PC Close Date & Time	23 SEP 2020 12:24

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 18:26
PC Open Date & Time	23 SEP 2020 13:19
PC Close Date & Time	24 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:42
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

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 ☒

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:44
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:46
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 20:15
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 22:12
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 SEP 2020 21:06

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 01 OCT 2020 20:24

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:13:34

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	30 SEP 2020 21:06
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:13:34

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	01 OCT 2020 20:24
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

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) _____

US3552191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date <i>(dd MMM yyyy)</i>	19 OCT 2020
Collection time <i>(00:00-23:59)</i>	10:25 (24 HR)
Collection date and time (derived)	19 OCT 2020 10:25

US3552191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:24

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 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 OCT 2020 21:26:08
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 22:08:49

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 21:03:28
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 NOV 2020 09:55:56
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	29 NOV 2020 17:52:18
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 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	08 DEC 2020 12:43:21
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 07:40:37
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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	20 DEC 2020 09:27:24
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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	26 DEC 2020 09:49:03
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 12:01:43
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 09:30:26
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 07:38:37
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 09:27:03

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 03:40:28

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 08:01:56
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 12:00:48

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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	19 FEB 2021 09:22:16
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 15:22:57

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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	05 MAR 2021 07:53:30
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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	12 MAR 2021 16:17:37
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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	19 MAR 2021 10:47:13
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 10:20:32

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 09:17:27

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 00:38:28

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 00:16:38
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 17:08:51

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 00:56:53

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

Patient Cloud Open Date & Time	10 SEP 2021 00:01
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Patient Cloud Close Date & Time	14 SEP 2021 23:59
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US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	05 NOV 2021 00:01
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Patient Cloud Close Date & Time	09 NOV 2021 23:59
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US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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08 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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15 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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01 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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04 MAR 2022 00:01

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08 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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07 JUN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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21 JUN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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28 JUN 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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01 JUL 2022 00:01

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05 JUL 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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12 JUL 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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19 JUL 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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16 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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23 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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26 AUG 2022 00:01

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30 AUG 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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

Date and time of submission

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06 SEP 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

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13 SEP 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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20 SEP 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:13:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 07:53:42

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:11

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:21:19

Generated On: 10 Jun 2021 08:13:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552191

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:21:19

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:24:50

Generated On: 10 Jun 2021 08:13:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	09:58 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 09:58
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552191

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3552191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	09:09 (24 HR)
Collection date and time (derived)	15 MAR 2021 09:09

US3552191

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 239 (1)

Form: Safety Call

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

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Safety Call Day 239 (1)

Form: Continuing

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

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552191

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Date of Contact	07 OCT 2020
Time of Contact	12:39
Date and Time of Contact (derived)	07 OCT 2020 12:39
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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"/>

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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

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

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

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

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

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

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EAB) (1725)

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US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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 (4)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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 OCT 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Form: Symptom Log (6)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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 OCT 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	98.3 F
-------------	--------

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

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

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

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

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Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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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Form: Symptom Log (7)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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 OCT 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	99 F
-------------	------

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

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

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

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

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Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Form: Symptom Log (8)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Symptom Day

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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 OCT 2020
------	-------------

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

O2 Saturation	88 %
---------------	------

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

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

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Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Form: Symptom Log (9)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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 OCT 2020
------	-------------

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

O2 Saturation	91 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Symptom Day

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

	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 OCT 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

Shortness of Breath	None	<input 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 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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"/>

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Date of Visit 8 OCT 2020

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

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

Date of Test 8 OCT 2020

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

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 OCT 2020
Day 5	Yes	12 OCT 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)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 08:30
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	111 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552191

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

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: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 OCT 2020

US3552191

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

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

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3552191

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

Date of updated informed consent (dd MMM yyyy) 13 JAN 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) 13 JAN 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 _____

US3552191

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	12:01 (24 HR)
Collection date and time (derived)	13 JAN 2021 12:01

US3552191

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 18:11:09

Generated On: 10 Jun 2021 08:13:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	12:04
Collection Date and Time (derived)	13 JAN 2021 12:04

US3552191

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 18:11:07

Generated On: 10 Jun 2021 08:13:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	24 SEP 2020
Start time (00:00-23:59)	18:42 (24 HR)
AE start date and time (derived)	24 SEP 2020 18:42
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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)	08 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)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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)	08 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)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

AEID	
Adverse event	SORE THROAT
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)	08 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)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

AEID

Adverse event

ANEMIA

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)

09 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)

20 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

AEID	
Adverse event	SINUS TACHYCARDIA
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)	09 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)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

AEID	
Adverse event	MUSCLE WEAKNESS
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)	09 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)	22 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	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

AEID	USA-US089-2021-MRNA-1273-P30 1000001
Adverse event	GRAVES' DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 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)	1 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	10 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 16 Apr 2021 18:02:33

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Number of Days in ICU	
Persistent or significant disability or incapacity	True
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 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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PER NOTES FROM PHYSICIAN'S PE TODAY AT CLINIC, SUBJECT HAS REACHED NEW BASELINE, HAS ONGOING FATIGUE AND NEEDS MEDICATIONS (SEE CON MEDS)

Narrative

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

SUBJECT HAS PREVIOUSLY REPORTED ADVERSE EVENTS OF PERIPHERAL EDEMA AND SHORTNESS OF BREATH (WITH THE FOLLOWING DETAILS: SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"; PCP

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

PRESCRIBED ATENOLOL FOR
SUBJECT, STARTED ON
30OCT2020. AS OF 11/18 PHONE
CALL, SUBJECT REPORTS THAT
PERIPHERAL EDEMA HAS
RESOLVED, SOB IS ONGOING)
ARE RETROSPECTIVELY,
CONSISTENT WITH
HYPERTHYROIDISM. AES OF
ANEMIA, SINUS
TACHYCARDIA, & MUSCLE
WEAKNESS ARE ALSO
RELATED TO THIS DIAGNOSIS
PER PI. PER PE TODAY AT
CLINIC (3/15), SUBJECT HAS
REACHED NEW BASELINE; HAS
ONGOING FATIGUE AND NEED
FOR MEDICATIONS.

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 (13)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

AEID

Adverse event

GENERALIZED ITCHING

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)

09 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

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) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES MELLITUS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (2)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication HCTZ / TRIAMTERENE

Prophylaxis Yes ☐
No ☒

Indication MENIERE'S DISEASE

Dose per administration 25 / 37.5

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 (2)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐
No ☒

Indication MILD 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 (4)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication REPLACEMENT FOR OR
PREVENTATIVE OF
METFORMIN DEPLETION

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 (5)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication CENTRUM SILVER

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

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 (8)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication GRAVES' DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication COREG

Prophylaxis Yes ☐
No ☒

Indication TACHYCARDIA

Dose per administration 6.25

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 (12)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication TACHYCARDIA

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 (14)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 NOV 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 (15)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication METHIMAZOLE

Prophylaxis Yes ☐
No ☒

Indication GRAVES' DISEASE

Dose per administration 30

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 (15)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 NOV 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) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication TACHYCARDIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 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 (17)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication METHIMAZOLE

Prophylaxis Yes ☐
No ☒

Indication GRAVES' DISEASE

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 (17)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 NOV 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ITCHING

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 (18)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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 (19)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication GRAVES' DISEASE

Dose per administration 30

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 (20)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PROPANOLOL

Prophylaxis Yes ☐
No ☒

Indication GRAVES DISEASE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 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)		17 JAN 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 (22)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐
No ☒

Indication GRAVE'S DISEASE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 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)		19 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication GRAVE'S DISEASE

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 (23)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 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)		23 DEC 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 (24)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication GRAVES DISEASE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 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"/>

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication GRAVES DISEASE

Dose per administration 15

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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US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 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)		06 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"/>

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication GRAVES DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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)	30 DEC 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"/>

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication GRAVES DISEASE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

	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)	14 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication GRAVES DISEASE

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 18:02:33

Generated On: 10 Jun 2021 08:13:34

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

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 18:11:08

Generated On: 10 Jun 2021 08:13:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 NOV 2020	RADIOACTIVE IODINE UPTAKE SCAN	Diagnostic	
01 DEC 2020	THYROID ABLATION	Adverse Event	

US3552191

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:13:34

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3552191

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:13:34

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 ☐

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	12/OCT/2020 08:43
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	13/OCT/2020 13:30
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	13/OCT/2020 15:24
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.	True

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:28
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:44
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:20
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	22/OCT/2020 17:23
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	26/OCT/2020 13:05
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	29/OCT/2020 11:07
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.	True

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (10)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	10/NOV/2020 19:08
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (11)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	12/NOV/2020 14:28
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (12)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	20/NOV/2020 21:48
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (13)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	23/NOV/2020 21:55
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

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (14)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	25/NOV/2020 12:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (15)

Data signed: (b) (4) 21 Feb 2021 18:11:10

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	15
Date of submission (Pre-filled from custom function)	04/JAN/2021 15:55
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

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2021-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	6

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2021-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	06/JAN/2021 09:47
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

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2021-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	06/JAN/2021 11:07
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.	True

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2021-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	07/JAN/2021 21:15
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

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2021-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	19/JAN/2021 10:29
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

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2021-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	16/MAR/2021 12:25
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

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Mar 2021 15:29:14

Generated On: 10 Jun 2021 08:13:34

SAEID	USA-US089-2021-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	16/MAR/2021 12:45
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

US3552191 (Prod: Saint Louis University)

US3552191

Form: Participant Creation

Generated On: 10 Jun 2021 08:13:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'US3552191'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:50:32

US3552191

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:05

US3552191

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:50:33

US3552191

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:05

US3552191

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'SCRN'	System	27 Aug 2020 14:51:05

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:50:34

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '66'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User entered 'YEARS'	System	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User entered '66'	System	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Female (F)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:13:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:26

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Aug 2020'	System	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2020'	System	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:58:47

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:50:33

US3552191

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:13:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'l'	System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:13:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:51:50

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:38:10
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 19:38:10
Data point term sent to Coder	System	27 Aug 2020 16:47:21
User entered 'DIABETES MELLiTUS type 2' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	27 Aug 2020 16:47:20
Data point term sent to Coder	System	27 Aug 2020 14:52:30
User entered 'diabetes mellitus'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Jun 2018'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:52:14
	(b) (4)	

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jun 2018'	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2018'	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:52:14

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear disorders NEC, PT: Meniere's disease, LLT: Meniere's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:42
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 19:21:42
Data point term sent to Coder	System	27 Aug 2020 14:53:31
User entered 'meniere's disease'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2015'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2015'	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2015'	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:52:46

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:21:42
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 19:21:42
Data point term sent to Coder	System	27 Aug 2020 14:53:32
User entered 'hypercholesterolemia'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:53:12
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:53:12
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:53:12

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2000'	System	27 Aug 2020 14:53:12

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2000'	System	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:53:12

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:46
Data point term sent to Coder	System	27 Aug 2020 14:55:34
User entered 'depression'	Stanley Doublin (b) (4)	27 Aug 2020 14:54:39
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1990'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Dublin (b) (4)	27 Aug 2020 14:54:39
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 1990'	System	27 Aug 2020 14:54:39

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '1990'	System	27 Aug 2020 14:54:39

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:54:39

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:22
Data point term sent to Coder	System	27 Aug 2020 14:57:35
User entered 'osteoarthritis'	Stanley Doublin (b) (4)	27 Aug 2020 14:56:50
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1987'	Stanley Doublin (b) (4)	27 Aug 2020 14:56:50

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 1987'	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '1987'	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:56:50

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:21
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 19:22:21
Data point term sent to Coder	System	27 Aug 2020 14:57:36
User entered 'vitamin d deficiency'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered 'un UNK 2012'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:57:13
	(b) (4)	

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:57:13
	(b) (4)	

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2012'	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2012'	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:57:13

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:22:21
Data point term sent to Coder	System	27 Aug 2020 14:57:36
User entered 'constipation'	Stanley Dublin (b) (4)	27 Aug 2020 14:57:34
	(b) (4)	

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered 'un UNK 2019'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:57:34
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Doublin (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2019'	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2019'	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:57:34

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:32
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 19:22:32
Data point term sent to Coder	System	27 Aug 2020 14:58:38
User entered 'seasonal allergies'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered 'un UNK 2017'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:57:47
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2017'	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2017'	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:57:47

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:22:31
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 19:22:31
Data point term sent to Coder	System	27 Aug 2020 14:58:37
User entered 'rosacea'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1990'	Stanley Dublin (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:58:02
	(b) (4)	

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 1990'	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '1990'	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:58:02

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:38:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:38:17
Data point term sent to Coder	System	27 Aug 2020 16:48:24
User entered 'BREAST CANCER' reason for change: Data Entry Error	Joan Siegner (b) (4)	27 Aug 2020 16:47:47
Data point term sent to Coder	System	27 Aug 2020 14:59:42
User entered 'breast cancer (Right)'	Stanley Doublin (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Jan 2007'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Jan 2012'	Stanley Dublin (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2007'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2007'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2012'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2012'	System	27 Aug 2020 14:58:53

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
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)	06 Sep 2020 22:01:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 22:01:36
Data point term sent to Coder	System	27 Aug 2020 15:00:43
User entered 'medication allergy: tolectin'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1987'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Stanley Doublin (b) (4)	27 Aug 2020 14:59:47
	(b) (4)	

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 1987'	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '1987'	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 14:59:47

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:10
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 19:23:10
Data point term sent to Coder	System	27 Aug 2020 15:00:43
User entered 'herniated disc'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 1987'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 15:00:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 15:00:33
User entered 'Yes (Y)' reason for change: Data Entry Error	System	27 Aug 2020 15:00:33
User opened query 'Data is required. Please complete.' (Site from System).	Stanley Dublin (b) (4)	27 Aug 2020 15:00:28
User entered empty.	(b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 1987'	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '1987'	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	27 Aug 2020 15:00:28

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 16:10:46
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 16:10:46
Data point term sent to Coder	System	03 Oct 2020 16:10:20
User entered 'menopause'	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un UNK 2003'	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Joan Siegner (b) (4) (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Joan Siegner (b) (4)	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Jan 2003'	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2003'	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	03 Oct 2020 16:09:33

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Achilles tendonitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:59:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:59:49
Data point term sent to Coder	System	19 Nov 2020 13:43:25
DataPoint Un-verified.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:42:33
Coding entries removed.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:42:33
User entered 'left heel ACHILLES TENDONITIS' reason for change: Data Entry Error	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:42:33
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of ACHILLES TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:21
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of ACHILLES TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'unknown at this time' (Site from DM).	Joan Siegner (b) (4)	26 Oct 2020 15:33:37
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of ACHILLES TENDONITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:53:11
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39

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Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Achilles tendonitis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 19:56:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 19:56:57
Data point term sent to Coder	System	07 Oct 2020 19:11:03
User entered 'achilles tendonitis'	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

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Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'un Mar 2020'	Joan Siegner (b) (4) (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4) (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Joan Siegner (b) (4) (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Joan Siegner (b) (4) (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Joan Siegner (b) (4)	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'Mar 2020'	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '2020'	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	07 Oct 2020 19:11:01

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:20:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:20:34
Data point term sent to Coder	System	08 Oct 2020 15:53:05
User entered 'seasonal allergies'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	08 Oct 2020 15:53:00

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 18:52:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 18:52:26
Data point term sent to Coder	System	12 Oct 2020 18:51:51
User entered 'obstructive sleep apnea'	Joan Siegner (b) (4) (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered empty.	Joan Siegner (b) (4) (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
User entered 'l'	Joan Siegner (b) (4) (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
DataPoint Verified.	(b) (4)	15 Oct 2020 14:22:39
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 14:22:39
	Joan Siegner (b) (4)	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered empty.	System	12 Oct 2020 18:51:41

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '13:00'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered '26 Aug 2020 13:00'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '65' in	(b) (4)	
	Stanley Dublin (b) (4)	27 Aug 2020 15:01:32
	(b) (4)	
DataPoint set to visible.	System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '171.2' lb	(b) (4) Stanley Dublin (b) (4)	27 Aug 2020 15:01:32
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
Amendment Manager: User entered '28.54874'	System	17 Sep 2020 00:04:23
User entered '28.5'	System	27 Aug 2020 15:01:32
DataPoint set to visible.	System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'kg/m2'	System	27 Aug 2020 15:01:32
DataPoint set to visible.	System	26 Aug 2020 19:58:54

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'bpm'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'breaths/min'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'mmHg'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User entered 'mmHg'	System	27 Aug 2020 15:01:32

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49

US3552191

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49

US3552191

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:41

US3552191

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:01:41

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:11:24
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 11:36:07
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'done' (Site from DM).	Joan Siegner (b) (4)	03 Oct 2020 16:09:06
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 09:31:45
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'un UNK 2003'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:13:34

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:27
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:02:15

US3552191

Folder: Screening

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[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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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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 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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[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 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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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 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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[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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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Folder: Screening

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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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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Folder: Screening

Form: Risk of Exposure

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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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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Form: Risk of Exposure

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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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'babysits grandchildren (ages 9, 5, and two are 3 years old) 1 - 3 times a week, grocery shopping twice a week, attends church services weekly, wears mask when out.'	(b) (4) Stanley Dublin (b) (4)	27 Aug 2020 15:04:54

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

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 21:26:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '0'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

[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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

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 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:13:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:26:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:04:54

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4)	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'VISIT1'	System	27 Aug 2020 15:05:04

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:59:24

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '188537'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:59:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 19:59:24

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

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 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

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 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	14 Sep 2020 19:11:59
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:15

US3552191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:13:34

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 17:31:02
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:08:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:08:00

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '13:00'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '26 Aug 2020 13:00'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '97.6' F	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '90'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'bpm'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '12'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'breaths/min'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '118'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '74'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:13:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:05:53

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '15:50'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '26 Aug 2020 15:50'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '97.9' F	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '80'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'bpm'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '16'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'breaths/min'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '122'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '72'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	27 Aug 2020 15:06:32

US3552191

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:38

US3552191

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4)	27 Aug 2020 15:06:38

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon trey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	26 Aug 2020 20:56:35
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	26 Aug 2020 20:56:35
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	26 Aug 2020 20:23:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

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 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	26 Aug 2020 20:56:35
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '15:20'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 20:56:35
User entered empty.	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'ONCE'	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 20:23:09

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '14:38'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '26 Aug 2020 14:38'	System	27 Aug 2020 15:06:54

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '26 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '14:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '26 Aug 2020 14:45'	System	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4)	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered empty.	System	27 Aug 2020 15:07:09

US3552191

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	02 Sep 2020 16:53:01

US3552191

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'I'	System	02 Sep 2020 16:53:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:58:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f' User entered 'Yes (Y)'	System	26 Aug 2020 20:59:06
	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:58:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f' User entered '97.1'	System	26 Aug 2020 20:59:06
	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:58:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f' User entered 'No (N)'	System	26 Aug 2020 20:59:06
	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '55257b81-0975-45fa-be2f-3d4299e2478f' User entered '26 Aug 2020 15:59'	System	26 Aug 2020 20:59:06
	System	26 Aug 2020 20:59:06

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 15:40'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:03:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd'	System	27 Aug 2020 16:04:21
User entered 'Yes (Y)'	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:03:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd' User entered '97.5'	System	27 Aug 2020 16:04:21
	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:04:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd'	System	27 Aug 2020 16:04:21
User entered 'No (N)'	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:04:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '78444e04-316a-4bb5-8bbc-37986aa748dd' User entered '27 Aug 2020 11:04'	System	27 Aug 2020 16:04:21
	System	27 Aug 2020 16:04:21

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 19:05'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 2'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:18:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0ace6'	System	28 Aug 2020 01:19:07
User entered 'Yes (Y)'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:18:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0ace6'	System	28 Aug 2020 01:19:07
User entered '99.5'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0ace6'	System	28 Aug 2020 01:19:07
User entered 'No (N)'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f99fe23-59ce-4a87-9342-e96dd1c0ace6'	System	28 Aug 2020 01:19:07
User entered '27 Aug 2020 20:19'	System	28 Aug 2020 01:19:07

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 3'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b'	System	29 Aug 2020 01:21:27
User entered 'Yes (Y)'	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b' User entered '99.9'	System	29 Aug 2020 01:21:27
	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b'	System	29 Aug 2020 01:21:27
User entered 'No (N)'	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6f1016f5-9ed8-49af-abe2-2db41898181b' User entered '28 Aug 2020 20:21'	System	29 Aug 2020 01:21:27
	System	29 Aug 2020 01:21:27

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 4'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19bc-6801-400c-a729-34bc530a506c' User entered 'Yes (Y)'	System	30 Aug 2020 00:24:51
	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19bc-6801-400c-a729-34bc530a506c' User entered '99.0'	System	30 Aug 2020 00:24:51
	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19bc-6801-400c-a729-34bc530a506c'	System	30 Aug 2020 00:24:51
User entered 'No (N)'	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3df19bc-6801-400c-a729-34bc530a506c' User entered '29 Aug 2020 19:24'	System	30 Aug 2020 00:24:51
	System	30 Aug 2020 00:24:51

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 5'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba' User entered 'Yes (Y)'	System	31 Aug 2020 00:13:25
	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba' User entered '98.7'	System	31 Aug 2020 00:13:25
	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba'	System	31 Aug 2020 00:13:25
User entered 'No (N)'	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '267f024b-84d4-41cb-a24b-53e61c589fba' User entered '30 Aug 2020 19:13'	System	31 Aug 2020 00:13:25
	System	31 Aug 2020 00:13:25

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 6'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266' User entered 'Yes (Y)'	System	01 Sep 2020 00:57:01
	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266' User entered '98.4'	System	01 Sep 2020 00:57:01
	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:54', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266'	System	01 Sep 2020 00:57:01
User entered 'No (N)'	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:56:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1dad7ba1-2b6d-44fd-a068-624a07cc8266'	System	01 Sep 2020 00:57:01
User entered '31 Aug 2020 19:56'	System	01 Sep 2020 00:57:01

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 7'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:38:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587'	System	02 Sep 2020 00:39:10
User entered 'Yes (Y)'	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587' User entered '98.9'	System	02 Sep 2020 00:39:10
	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587'	System	02 Sep 2020 00:39:10
User entered 'No (N)'	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd109a038-47c7-4e22-88fb-b57f314d5587'	System	02 Sep 2020 00:39:10
User entered '01 Sep 2020 19:39'	System	02 Sep 2020 00:39:10

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'None (1)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'No (N)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'No (N)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf'	System	26 Aug 2020 20:59:33
User entered 'None (1)'	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '48f6a82e-c7c6-418b-902e-5dcfe38ca1cf' User entered '26 Aug 2020 15:59'	System	26 Aug 2020 20:59:33
	System	26 Aug 2020 20:59:33

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 15:40'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:04:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'None (1)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'No (N)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'No (N)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:37', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered 'None (1)'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f6b5851e-d94e-4a3a-9705-be23da5741f2'	System	27 Aug 2020 16:05:48
User entered '27 Aug 2020 11:05'	System	27 Aug 2020 16:05:48

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 19:05'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 2'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'laf9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'No (N)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'No (N)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1afd9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered 'None (1)'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'laf9ced-d114-4d27-9e6c-b099e4eb9730'	System	28 Aug 2020 01:19:40
User entered '27 Aug 2020 20:19'	System	28 Aug 2020 01:19:40

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 3'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'No (N)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'No (N)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:40', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered 'None (1)'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9e5b801c-7d75-401b-83fd-e68d1162f823'	System	29 Aug 2020 01:21:51
User entered '28 Aug 2020 20:21'	System	29 Aug 2020 01:21:51

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 4'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:24:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'No (N)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'No (N)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8'	System	30 Aug 2020 00:25:17
User entered 'None (1)'	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '09df3756-a299-4f68-a816-074f7922dfa8' User entered '29 Aug 2020 19:25'	System	30 Aug 2020 00:25:17
	System	30 Aug 2020 00:25:17

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 5'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'None (1)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'No (N)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'No (N)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered 'None (1)'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '16d26174-73d8-4456-b265-ba6d6e6fa100'	System	31 Aug 2020 00:15:38
User entered '30 Aug 2020 19:13'	System	31 Aug 2020 00:15:38

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 6'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'None (1)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'No (N)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'No (N)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered 'None (1)'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3868d94-c1ef-4360-a0d0-742094fffb07'	System	01 Sep 2020 00:57:22
User entered '31 Aug 2020 19:57'	System	01 Sep 2020 00:57:22

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 7'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'None (1)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'No (N)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'No (N)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered 'None (1)'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a246c79-a7f5-4020-a0b7-c4234f32d238'	System	02 Sep 2020 00:39:29
User entered '01 Sep 2020 19:39'	System	02 Sep 2020 00:39:29

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:39', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2' User entered 'None (0)'	System	26 Aug 2020 21:00:07
	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:44', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2' User entered 'None (0)'	System	26 Aug 2020 21:00:07
	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:48', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'None (0)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T15:59:52', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered 'No (N)'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-26T16:00:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '8163f7b9-1022-445a-8c39-f9ba074cd8c2'	System	26 Aug 2020 21:00:07
User entered '26 Aug 2020 16:00'	System	26 Aug 2020 21:00:07

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 15:40'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001' User entered 'None (0)'	System	27 Aug 2020 16:06:19
	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:54', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001' User entered 'None (0)'	System	27 Aug 2020 16:06:19
	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:05:57', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001' User entered 'None (0)'	System	27 Aug 2020 16:06:19
	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001' User entered 'None (0)'	System	27 Aug 2020 16:06:19
	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:02', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001' User entered 'None (0)'	System	27 Aug 2020 16:06:19
	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001' User entered 'None (0)'	System	27 Aug 2020 16:06:19
	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001'	System	27 Aug 2020 16:06:19
User entered 'No (N)'	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T11:06:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '47d7020b-930c-46e0-906a-3b3e73ce5001' User entered '27 Aug 2020 11:06'	System	27 Aug 2020 16:06:19
	System	27 Aug 2020 16:06:19

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Aug 2020 19:05'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 2'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:19:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e'	System	28 Aug 2020 01:20:24
User entered 'Some interference with activity (2)'	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'None (0)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered 'No (N)'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-27T20:20:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9dc9c4e3-7060-4952-ba37-bc67c276587e' User entered '27 Aug 2020 20:20'	System	28 Aug 2020 01:20:24
	System	28 Aug 2020 01:20:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 3'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:21:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8' User entered 'None (0)'	System	29 Aug 2020 01:22:24
	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8' User entered 'None (0)'	System	29 Aug 2020 01:22:24
	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'None (0)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:11', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered 'No (N)'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-28T20:22:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '930dd489-6df5-46e6-acad-a2661424def8'	System	29 Aug 2020 01:22:24
User entered '28 Aug 2020 20:22'	System	29 Aug 2020 01:22:24

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 4'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'None (0)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'No interference with activity (1)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c' User entered 'None (0)'	System	30 Aug 2020 00:25:47
	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c' User entered 'None (0)'	System	30 Aug 2020 00:25:47
	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c' User entered 'None (0)'	System	30 Aug 2020 00:25:47
	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c' User entered 'None (0)'	System	30 Aug 2020 00:25:47
	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered 'No (N)'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-29T19:25:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '101211df-0847-46ff-9c15-7d5fdbd8632c'	System	30 Aug 2020 00:25:47
User entered '29 Aug 2020 19:25'	System	30 Aug 2020 00:25:47

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 5'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:44', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b' User entered 'None (0)'	System	31 Aug 2020 00:15:50
	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b' User entered 'None (0)'	System	31 Aug 2020 00:15:50
	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b' User entered 'None (0)'	System	31 Aug 2020 00:15:50
	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b' User entered 'None (0)'	System	31 Aug 2020 00:15:50
	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b' User entered 'None (0)'	System	31 Aug 2020 00:15:50
	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b' User entered 'None (0)'	System	31 Aug 2020 00:15:50
	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:13:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered 'No (N)'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-30T19:14:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '262cf109-2835-48d0-ab6b-d37cb42a5f1b'	System	31 Aug 2020 00:15:50
User entered '30 Aug 2020 19:14'	System	31 Aug 2020 00:15:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 6'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered 'None (0)'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered 'None (0)'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered 'None (0)'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:33', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered 'None (0)'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered 'None (0)'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered 'None (0)'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered 'No (N)'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-08-31T19:57:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '935a00d0-9f85-46f2-a9fc-bd8469af02e0' User entered '31 Aug 2020 19:57'	System	01 Sep 2020 00:57:50
	System	01 Sep 2020 00:57:50

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 7'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'None (0)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'None (0)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:33', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'None (0)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'None (0)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'None (0)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'None (0)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:42', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered 'No (N)'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-01T19:39:48', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ca2dbb0c-b636-49f7-b448-e8ea6548a81a' User entered '01 Sep 2020 19:39'	System	02 Sep 2020 00:39:51
	System	02 Sep 2020 00:39:51

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 20:56:35

US3552191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '02 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 15:21:43
User entered '2 Sep 2020'	Joan Siegner (b) (4) [REDACTED]	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Joan Siegner (b) (4)	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Joan Siegner (b) (4)	02 Sep 2020 16:53:21

US3552191

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:02

US3552191

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'l'	System	09 Sep 2020 19:57:02

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '09 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 15:21:29
User entered '9 Sep 2020'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered empty.	Heather Douds (b) (4) (b) (4)	09 Sep 2020 19:57:10

US3552191

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:05

US3552191

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'I'	System	16 Sep 2020 17:20:05

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '16 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered empty.	Stanley Dublin (b) (4) (b) (4)	16 Sep 2020 17:20:26

US3552191

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	23 Sep 2020 14:22:24

US3552191

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'l'	System	23 Sep 2020 14:22:24

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4)	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'VISIT2'	System	23 Sep 2020 17:14:57

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '08:55'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '23 Sep 2020 08:55'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '98.3' F	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '97'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'bpm'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '14'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'breaths/min'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '119'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '71'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	23 Sep 2020 17:15:22

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '10:04'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '23 Sep 2020 10:04'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '98.4' F	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '90'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'bpm'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '14'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'breaths/min'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '119'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '72'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'mmHg'	System	23 Sep 2020 17:17:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:20:53

US3552191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:20:53

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

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 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '23 Sep 2020'	Cassandra Zehenny (b) (4) (b) (4)	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '09:34'	Cassandra Zehenny (b) (4) (b) (4)	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '23 Sep 2020 09:34'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Left Arm (LEFT ARM)'	Cassandra Zehenny (b) (4) (b) (4)	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'ONCE'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:13:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 14:40:04

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '09:12'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '23 Sep 2020 09:12'	System	23 Sep 2020 17:21:05

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '23 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '09:15'	(b) (4) Stanley Dublin (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '23 Sep 2020 09:15'	System	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered empty.	(b) (4) Stanley Dublin (b) (4)	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered empty.	System	23 Sep 2020 17:21:17

US3552191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	30 Sep 2020 17:04:09

US3552191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'I'	System	30 Sep 2020 17:04:09

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:02:50', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea' User entered 'Yes (Y)'	System	23 Sep 2020 15:03:21
	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:02:57', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea' User entered '98.4'	System	23 Sep 2020 15:03:21
	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea'	System	23 Sep 2020 15:03:21
User entered 'No (N)'	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cfa8b757-8ee9-4a8c-95c8-9d9ba6c0a6ea' User entered '23 Sep 2020 10:03'	System	23 Sep 2020 15:03:21
	System	23 Sep 2020 15:03:21

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 09:54'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 12:24'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e' User entered 'Yes (Y)'	System	23 Sep 2020 23:25:26
	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e' User entered '97.3'	System	23 Sep 2020 23:25:26
	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e'	System	23 Sep 2020 23:25:26
User entered 'No (N)'	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a3205a4c-2afb-4491-96d7-dae5258c183e' User entered '23 Sep 2020 18:25'	System	23 Sep 2020 23:25:26
	System	23 Sep 2020 23:25:26

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 13:19'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 2'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd' User entered 'Yes (Y)'	System	24 Sep 2020 23:40:02
	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:50', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd' User entered '101.2'	System	24 Sep 2020 23:40:02
	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd'	System	24 Sep 2020 23:40:02
User entered 'No (N)'	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:39:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '847734cf-81b8-4127-9627-94066ba4e1cd' User entered '24 Sep 2020 18:39'	System	24 Sep 2020 23:40:02
	System	24 Sep 2020 23:40:02

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 3'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:57:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f' User entered 'Yes (Y)'	System	25 Sep 2020 23:58:24
	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f' User entered '98.8'	System	25 Sep 2020 23:58:24
	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f' User entered 'No (N)'	System	25 Sep 2020 23:58:24
	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ce2045ca-96f9-4d35-a279-dfc64b95208f' User entered '25 Sep 2020 18:58'	System	25 Sep 2020 23:58:24
	System	25 Sep 2020 23:58:24

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 4'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8'	System	27 Sep 2020 00:43:25
User entered 'Yes (Y)'	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8' User entered '98.7'	System	27 Sep 2020 00:43:25
	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:19', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8'	System	27 Sep 2020 00:43:25
User entered 'No (N)'	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '3a8ac345-dca9-435d-b09b-44a1429ad9f8'	System	27 Sep 2020 00:43:25
User entered '26 Sep 2020 19:43'	System	27 Sep 2020 00:43:25

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 5'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-eb98b01704c9' User entered 'Yes (Y)'	System	27 Sep 2020 23:45:34
	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:24', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-cb98b01704c9' User entered '98.1'	System	27 Sep 2020 23:45:34
	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-eb98b01704c9' User entered 'No (N)'	System	27 Sep 2020 23:45:34
	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5d039890-2daa-49a7-a6b0-eb98b01704c9' User entered '27 Sep 2020 18:45'	System	27 Sep 2020 23:45:34
	System	27 Sep 2020 23:45:34

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 6'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507'	System	29 Sep 2020 01:14:23
User entered 'Yes (Y)'	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507' User entered '99.0'	System	29 Sep 2020 01:14:23
	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507'	System	29 Sep 2020 01:14:23
User entered 'No (N)'	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c8a88475-f1b5-4cf8-ae21-f913e46cc507'	System	29 Sep 2020 01:14:23
User entered '28 Sep 2020 20:14'	System	29 Sep 2020 01:14:23

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 7'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbed57-5643-473c-b49d-5d4b59f43b16' User entered 'Yes (Y)'	System	30 Sep 2020 03:11:28
	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbcd57-5643-473c-b49d-5d4b59f43b16' User entered '98.7'	System	30 Sep 2020 03:11:28
	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbed57-5643-473c-b49d-5d4b59f43b16'	System	30 Sep 2020 03:11:28
User entered 'No (N)'	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f0fbcd57-5643-473c-b49d-5d4b59f43b16'	System	30 Sep 2020 03:11:28
User entered '29 Sep 2020 22:11'	System	30 Sep 2020 03:11:28

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e'	System	23 Sep 2020 15:03:44
User entered 'None (1)'	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e' User entered 'No (N)'	System	23 Sep 2020 15:03:44
	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e' User entered 'No (N)'	System	23 Sep 2020 15:03:44
	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:33', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e'	System	23 Sep 2020 15:03:44
User entered 'None (1)'	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:40', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cc5f2165-e4f1-40c3-a9ef-e2d45f50378e' User entered '23 Sep 2020 10:03'	System	23 Sep 2020 15:03:44
	System	23 Sep 2020 15:03:44

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 09:54'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 12:24'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f' User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 23:25:48
	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f' User entered 'No (N)'	System	23 Sep 2020 23:25:48
	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f' User entered 'No (N)'	System	23 Sep 2020 23:25:48
	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f' User entered 'None (1)'	System	23 Sep 2020 23:25:48
	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'f1db838e-fa4d-4c65-9505-09716694d41f' User entered '23 Sep 2020 18:25'	System	23 Sep 2020 23:25:48
	System	23 Sep 2020 23:25:48

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 13:19'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 2'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'No (N)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'No (N)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:40:39', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3'	System	24 Sep 2020 23:41:08
User entered 'None (1)'	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2c99dfa8-8f14-4377-9c60-ded3f9e0f8f3' User entered '24 Sep 2020 18:41'	System	24 Sep 2020 23:41:08
	System	24 Sep 2020 23:41:08

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 3'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'No (N)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'No (N)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered 'None (1)'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '4242ef3d-c71d-44a4-89ce-e295a64f75d0'	System	25 Sep 2020 23:58:55
User entered '25 Sep 2020 18:58'	System	25 Sep 2020 23:58:55

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 4'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'No (N)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'No (N)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:43:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9'	System	27 Sep 2020 00:44:05
User entered 'None (1)'	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1f13cce3-1723-4eb5-adca-08ceada098f9' User entered '26 Sep 2020 19:44'	System	27 Sep 2020 00:44:05
	System	27 Sep 2020 00:44:05

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 5'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:40', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'No (N)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'No (N)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:45:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49'	System	27 Sep 2020 23:46:06
User entered 'None (1)'	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '26861370-fddb-4d77-8575-c963bf71fb49' User entered '27 Sep 2020 18:46'	System	27 Sep 2020 23:46:06
	System	27 Sep 2020 23:46:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 6'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'No (N)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:36', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'No (N)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:48', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered 'None (1)'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:50', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '59fc4a44-a941-438b-850b-fc0e5fd5b239'	System	29 Sep 2020 01:14:53
User entered '28 Sep 2020 20:14'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 7'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075'	System	30 Sep 2020 03:12:06
User entered 'None (1)'	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:39', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075' User entered 'No (N)'	System	30 Sep 2020 03:12:06
	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:44', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075' User entered 'No (N)'	System	30 Sep 2020 03:12:06
	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:11:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075'	System	30 Sep 2020 03:12:06
User entered 'None (1)'	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6093be30-4c21-4bc8-83d8-9ab3c1678075' User entered '29 Sep 2020 22:12'	System	30 Sep 2020 03:12:06
	System	30 Sep 2020 03:12:06

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073' User entered 'None (0)'	System	23 Sep 2020 15:04:11
	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073' User entered 'None (0)'	System	23 Sep 2020 15:04:11
	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073' User entered 'None (0)'	System	23 Sep 2020 15:04:11
	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:54', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073' User entered 'None (0)'	System	23 Sep 2020 15:04:11
	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073' User entered 'None (0)'	System	23 Sep 2020 15:04:11
	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:03:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073' User entered 'None (0)'	System	23 Sep 2020 15:04:11
	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:04:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073'	System	23 Sep 2020 15:04:11
User entered 'No (N)'	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T10:04:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'daa05262-3604-449c-8385-e0d61f8b4073' User entered '23 Sep 2020 10:04'	System	23 Sep 2020 15:04:11
	System	23 Sep 2020 15:04:11

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 09:54'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 12:24'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:52', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538' User entered 'None (0)'	System	23 Sep 2020 23:26:20
	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538' User entered 'None (0)'	System	23 Sep 2020 23:26:20
	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:25:58', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538' User entered 'None (0)'	System	23 Sep 2020 23:26:20
	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538' User entered 'None (0)'	System	23 Sep 2020 23:26:20
	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:05', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538' User entered 'None (0)'	System	23 Sep 2020 23:26:20
	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538' User entered 'None (0)'	System	23 Sep 2020 23:26:20
	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:11', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered 'No (N)'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-23T18:26:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c355627b-788f-42e8-97de-fa6973b0e538'	System	23 Sep 2020 23:26:20
User entered '23 Sep 2020 18:26'	System	23 Sep 2020 23:26:20

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '23 Sep 2020 13:19'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 2'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'No interference with activity (1)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'Some interference with activity (2)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'Some interference with activity (2)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:37', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'Some interference with activity (2)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b' User entered 'None (0)'	System	24 Sep 2020 23:42:17
	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b'	System	24 Sep 2020 23:42:17
User entered 'No interference with activity (1)'	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:41:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b' User entered 'No (N)'	System	24 Sep 2020 23:42:17
	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-24T18:42:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bfe6cd49-97f3-413c-9d8b-a3e95cc4910b' User entered '24 Sep 2020 18:42'	System	24 Sep 2020 23:42:17
	System	24 Sep 2020 23:42:17

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 3'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:58:57', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'Some interference with activity (2)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:11', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07' User entered 'None (0)'	System	25 Sep 2020 23:59:33
	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered 'No (N)'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-25T18:59:30', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '95248dcf-b95e-41e3-9061-f7e740c55f07'	System	25 Sep 2020 23:59:33
User entered '25 Sep 2020 18:59'	System	25 Sep 2020 23:59:33

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 4'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered 'Some interference with activity (2)'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:19', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered 'None (0)'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff'	System	27 Sep 2020 00:44:49
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered 'No (N)'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-26T19:44:46', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0f380255-a160-4f95-b2ec-7da821ad4eff' User entered '26 Sep 2020 19:44'	System	27 Sep 2020 00:44:49
	System	27 Sep 2020 00:44:49

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 5'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:13', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'Some interference with activity (2)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:24', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42' User entered 'None (0)'	System	27 Sep 2020 23:46:42
	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'None (0)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered 'No (N)'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-27T18:46:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'aed399f8-d68e-439b-beb8-25ab738e9a42'	System	27 Sep 2020 23:46:42
User entered '27 Sep 2020 18:46'	System	27 Sep 2020 23:46:42

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 6'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:14:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca' User entered 'None (0)'	System	29 Sep 2020 01:15:30
	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'Some interference with activity (2)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca' User entered 'None (0)'	System	29 Sep 2020 01:15:30
	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca' User entered 'None (0)'	System	29 Sep 2020 01:15:30
	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:09', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca' User entered 'None (0)'	System	29 Sep 2020 01:15:30
	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca' User entered 'None (0)'	System	29 Sep 2020 01:15:30
	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered 'No (N)'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-28T20:15:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '874ebbd9-09cf-4d69-84be-fb5d0e8f98ca'	System	29 Sep 2020 01:15:30
User entered '28 Sep 2020 20:15'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	23 Sep 2020 14:40:04
User entered 'Day 7'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:06', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8' User entered 'None (0)'	System	30 Sep 2020 03:12:46
	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'No interference with activity (1)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8' User entered 'None (0)'	System	30 Sep 2020 03:12:46
	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8' User entered 'None (0)'	System	30 Sep 2020 03:12:46
	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8' User entered 'None (0)'	System	30 Sep 2020 03:12:46
	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8' User entered 'None (0)'	System	30 Sep 2020 03:12:46
	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8'	System	30 Sep 2020 03:12:46
User entered 'No (N)'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-29T22:12:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1282dbd6-6341-4a30-a676-4df4cc67adf8' User entered '29 Sep 2020 22:12'	System	30 Sep 2020 03:12:46
	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:40:04

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	29 Sep 2020 01:15:30
User entered 'Day 8'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6cc956df-2b79-4b39-8bf1-462559a187b3'	System	01 Oct 2020 02:06:29
User entered 'No interference with activity (1)'	System	01 Oct 2020 02:06:29

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6cc956df-2b79-4b39-8bf1-462559a187b3'	System	01 Oct 2020 02:06:29
User entered '30 Sep 2020 21:06'	System	01 Oct 2020 02:06:29

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:15:30

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	30 Sep 2020 03:12:46
User entered 'Day 9'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:14', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ac0c65ff-cde8-4f56-b277-a8d116c2308d' User entered 'None (0)'	System	02 Oct 2020 01:24:20
	System	02 Oct 2020 01:24:20

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:13:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ac0c65ff-cde8-4f56-b277-a8d116c2308d' User entered '01 Oct 2020 20:24'	System	02 Oct 2020 01:24:20
	System	02 Oct 2020 01:24:20

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	29 Sep 2020 01:14:53
User entered 'Day 8'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '77861b4b-0ccd-4a06-9f10-d37c5820b7af' User entered 'No (N)'	System	01 Oct 2020 02:06:38
	System	01 Oct 2020 02:06:38

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-09-30T21:06:35', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '77861b4b-0ccd-4a06-9f10-d37c5820b7af' User entered '30 Sep 2020 21:06'	System	01 Oct 2020 02:06:38
	System	01 Oct 2020 02:06:38

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:14:53

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	30 Sep 2020 03:12:46
User entered 'Day 9'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:13:34

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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ea9e862a-4425-430d-a5cf-d38be9077f7d' User entered 'No (N)'	System	02 Oct 2020 01:24:27
	System	02 Oct 2020 01:24:27

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:13:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-01T20:24:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'ea9e862a-4425-430d-a5cf-d38be9077f7d' User entered '01 Oct 2020 20:24'	System	02 Oct 2020 01:24:27
	System	02 Oct 2020 01:24:27

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:13:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 03:12:46

US3552191

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:13:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 03:12:46

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '30 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered empty.	Stanley Dublin (b) (4) (b) (4)	30 Sep 2020 17:04:18

US3552191

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	07 Oct 2020 18:44:31

US3552191

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'l'	System	07 Oct 2020 18:44:31

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	Joan Siegner (b) (4)	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '7 Oct 2020'	(b) (4) Joan Siegner (b) (4)	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Joan Siegner (b) (4)	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered empty.	Joan Siegner (b) (4) [REDACTED]	07 Oct 2020 18:44:43

US3552191

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:47

US3552191

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'l'	System	14 Oct 2020 15:22:47

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '14 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:22:55

US3552191

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:08

US3552191

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'l'	System	19 Oct 2020 19:26:08

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '19 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'VISIT3'	System	19 Oct 2020 19:26:16

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered empty.	System	19 Oct 2020 19:27:05

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45

US3552191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45

US3552191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:11

US3552191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '19 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:11

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered '19 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:24
User entered '10:25'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered '19 Oct 2020 10:25'	System	19 Oct 2020 19:27:23

US3552191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:24
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:14:52

US3552191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'I'	System	19 Nov 2020 13:14:52

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 64'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:17', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'Yes (Y)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'No (N)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:29', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440' User entered 'No (N)'	System	27 Oct 2020 02:26:17
	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

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)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'Yes (Y)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Please 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)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:25:51', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440'	System	27 Oct 2020 02:26:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-10-26T21:26:08', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b5a4c9c6-8d75-4379-acc2-beb458871440' User entered '26 Oct 2020 21:26:08'	System	27 Oct 2020 02:26:17
	System	27 Oct 2020 02:26:17

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 71'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-04T22:08:20', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2fcb33e0-82d3-4ed8-aba3-c88dbf8073ec'	System	05 Nov 2020 04:08:55
User entered 'No (N)'	System	05 Nov 2020 04:08:55

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-04T22:08:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2fcb33e0-82d3-4ed8-aba3-c88dbf8073ec'	System	05 Nov 2020 04:08:55
User entered 'No (N)'	System	05 Nov 2020 04:08:55

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-04T22:08:49', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '2fcb33e0-82d3-4ed8-aba3-c88dbf8073ec' User entered '04 Nov 2020 22:08:49'	System	05 Nov 2020 04:08:55
	System	05 Nov 2020 04:08:55

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered 'Day 78'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-09T21:03:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd958c541-a41b-4b3f-a565-b6a1d6e32aa1'	System	10 Nov 2020 03:03:31
User entered 'No (N)'	System	10 Nov 2020 03:03:31

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-09T21:03:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd958c541-a41b-4b3f-a565-b6a1d6e32aa1'	System	10 Nov 2020 03:03:31
User entered 'No (N)'	System	10 Nov 2020 03:03:31

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-09T21:03:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd958c541-a41b-4b3f-a565-b6a1d6e32aa1' User entered '09 Nov 2020 21:03:28'	System	10 Nov 2020 03:03:31
	System	10 Nov 2020 03:03:31

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 20:56:35

US3552191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:07:53
Data entry locked.	System	26 Aug 2020 20:56:35
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 20:56:35

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-24T09:55:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bbf3025a-c4f0-4cc9-8e04-9b3a638f6f3f' User entered 'No (N)'	System	24 Nov 2020 15:55:58

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-24T09:55:41', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bbf3025a-c4f0-4cc9-8e04-9b3a638f6f3f' User entered 'No (N)'	System	24 Nov 2020 15:55:58

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-24T09:55:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'bbf3025a-c4f0-4cc9-8e04-9b3a638f6f3f' User entered '24 Nov 2020 09:55:56'	System	24 Nov 2020 15:55:58
	System	24 Nov 2020 15:55:58

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-29T17:51:42', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd146ac05-e2b9-4838-80c6-15b801fab181' User entered 'Yes (Y)'	System	29 Nov 2020 23:52:27
	System	29 Nov 2020 23:52:27

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-29T17:51:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd146ac05-e2b9-4838-80c6-15b801fab181' User entered 'No (N)'	System	29 Nov 2020 23:52:27

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-29T17:51:52', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd146ac05-e2b9-4838-80c6-15b801fab181' User entered 'No (N)'	System	29 Nov 2020 23:52:27
	System	29 Nov 2020 23:52:27

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-29T17:51:57', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd146ac05-e2b9-4838-80c6-15b801fab181'	System	29 Nov 2020 23:52:27
User entered 'Yes (Y)'	System	29 Nov 2020 23:52:27

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Please 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-29T17:52:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd146ac05-e2b9-4838-80c6-15b801fab181'	System	29 Nov 2020 23:52:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 23:52:27

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-11-29T17:52:18', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd146ac05-e2b9-4838-80c6-15b801fab181' User entered '29 Nov 2020 17:52:18'	System	29 Nov 2020 23:52:27
	System	29 Nov 2020 23:52:27

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-08T12:42:53', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '87ec9ec7-db03-4fe7-ac27-08cef0a7ffe7'	System	08 Dec 2020 18:43:33
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-08T12:43:01', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '87ec9ec7-db03-4fe7-ac27-08cef0a7ffe7'	System	08 Dec 2020 18:43:33
User entered 'No (N)'	System	08 Dec 2020 18:43:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-08T12:43:04', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '87ec9ec7-db03-4fe7-ac27-08cef0a7ffe7'	System	08 Dec 2020 18:43:33
User entered 'No (N)'	System	08 Dec 2020 18:43:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-08T12:43:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '87ec9ec7-db03-4fe7-ac27-08cef0a7ffe7'	System	08 Dec 2020 18:43:33
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Please 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-08T12:43:12', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '87ec9ec7-db03-4fe7-ac27-08cef0a7ffe7'	System	08 Dec 2020 18:43:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Dec 2020 18:43:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-08T12:43:21', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '87ec9ec7-db03-4fe7-ac27-08cef0a7ffe7'	System	08 Dec 2020 18:43:33
User entered '08 Dec 2020 12:43:21'	System	08 Dec 2020 18:43:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-11T07:40:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1b09031f-0f3d-41a8-ab17-7da6b6e7d53d' User entered 'No (N)'	System	11 Dec 2020 13:40:39
	System	11 Dec 2020 13:40:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-11T07:40:31', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1b09031f-0f3d-41a8-ab17-7da6b6e7d53d' User entered 'No (N)'	System	11 Dec 2020 13:40:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-11T07:40:37', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1b09031f-0f3d-41a8-ab17-7da6b6e7d53d' User entered '11 Dec 2020 07:40:37'	System	11 Dec 2020 13:40:39
	System	11 Dec 2020 13:40:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-20T09:27:15', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1eca5d7b-af9a-42bd-9127-fabf55c35268' User entered 'No (N)'	System	20 Dec 2020 15:27:26

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-20T09:27:19', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1eca5d7b-af9a-42bd-9127-fabf55c35268' User entered 'No (N)'	System	20 Dec 2020 15:27:26

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-20T09:27:24', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1eca5d7b-af9a-42bd-9127-fabf55c35268' User entered '20 Dec 2020 09:27:24'	System	20 Dec 2020 15:27:26
	System	20 Dec 2020 15:27:26

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-26T09:48:55', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0a9804fb-b883-4c6a-bb4a-37ca0874367a' User entered 'No (N)'	System	26 Dec 2020 15:49:09
	System	26 Dec 2020 15:49:09

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-26T09:48:59', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0a9804fb-b883-4c6a-bb4a-37ca0874367a' User entered 'No (N)'	System	26 Dec 2020 15:49:09
	System	26 Dec 2020 15:49:09

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2020-12-26T09:49:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0a9804fb-b883-4c6a-bb4a-37ca0874367a' User entered '26 Dec 2020 09:49:03'	System	26 Dec 2020 15:49:09
	System	26 Dec 2020 15:49:09

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-03T12:01:34', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7cfed127-ecbb-472a-8584-201805308911' User entered 'No (N)'	System	03 Jan 2021 18:01:47
	System	03 Jan 2021 18:01:47

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-03T12:01:38', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7cfed127-ecbb-472a-8584-201805308911'	System	03 Jan 2021 18:01:47
User entered 'No (N)'	System	03 Jan 2021 18:01:47

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-03T12:01:43', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7cfed127-ecbb-472a-8584-201805308911' User entered '03 Jan 2021 12:01:43'	System	03 Jan 2021 18:01:47
	System	03 Jan 2021 18:01:47

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-09T09:30:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9729ccfe-e5e0-4e98-a636-7d68aafa07e4' User entered 'No (N)'	System	09 Jan 2021 15:30:30

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-09T09:30:22', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9729ccfe-e5e0-4e98-a636-7d68aafa07e4' User entered 'No (N)'	System	09 Jan 2021 15:30:30

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-09T09:30:26', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '9729ccfe-e5e0-4e98-a636-7d68aafa07e4' User entered '09 Jan 2021 09:30:26'	System	09 Jan 2021 15:30:30
	System	09 Jan 2021 15:30:30

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-15T07:38:27', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b4377b31-0ae8-41ac-ae9f-66b35b4be448'	System	15 Jan 2021 13:38:39
User entered 'No (N)'	System	15 Jan 2021 13:38:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-15T07:38:32', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b4377b31-0ae8-41ac-ae9f-66b35b4be448' User entered 'No (N)'	System	15 Jan 2021 13:38:39
	System	15 Jan 2021 13:38:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-15T07:38:37', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'b4377b31-0ae8-41ac-ae9f-66b35b4be448' User entered '15 Jan 2021 07:38:37'	System	15 Jan 2021 13:38:39
	System	15 Jan 2021 13:38:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-22T09:26:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6b7895ee-cbc9-43ee-85ec-f86cd34abdbc' User entered 'No (N)'	System	22 Jan 2021 15:27:05

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-22T09:27:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6b7895ee-cbc9-43ee-85ec-f86cd34abdbc' User entered 'No (N)'	System	22 Jan 2021 15:27:05

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-22T09:27:03', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6b7895ee-cbc9-43ee-85ec-f86cd34abdbc' User entered '22 Jan 2021 09:27:03'	System	22 Jan 2021 15:27:05
	System	22 Jan 2021 15:27:05

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-31T03:40:23', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3a79e9d-3d7f-45e2-a1f3-69dd2b543012'	System	31 Jan 2021 09:40:32
User entered 'No (N)'	System	31 Jan 2021 09:40:32

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-31T03:40:25', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3a79e9d-3d7f-45e2-a1f3-69dd2b543012'	System	31 Jan 2021 09:40:32
User entered 'No (N)'	System	31 Jan 2021 09:40:32

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-01-31T03:40:28', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'c3a79e9d-3d7f-45e2-a1f3-69dd2b543012' User entered '31 Jan 2021 03:40:28'	System	31 Jan 2021 09:40:32
	System	31 Jan 2021 09:40:32

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-05T08:01:47', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a82cca58-f530-4f7c-910e-6ff53f400398' User entered 'No (N)'	System	05 Feb 2021 14:02:00

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-05T08:01:52', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a82cca58-f530-4f7c-910e-6ff53f400398' User entered 'No (N)'	System	05 Feb 2021 14:02:00

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-05T08:01:56', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a82cca58-f530-4f7c-910e-6ff53f400398'	System	05 Feb 2021 14:02:00
User entered '05 Feb 2021 08:01:56'	System	05 Feb 2021 14:02:00

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-14T12:00:42', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a4a3cbaf-724f-48af-a11d-58bfb3334449' User entered 'No (N)'	System	16 Feb 2021 18:12:39
	System	16 Feb 2021 18:12:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-14T12:00:45', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a4a3cbaf-724f-48af-a11d-58bfb3334449' User entered 'No (N)'	System	16 Feb 2021 18:12:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-14T12:00:48', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'a4a3cbaf-724f-48af-a11d-58bfb3334449' User entered '14 Feb 2021 12:00:48'	System	16 Feb 2021 18:12:39

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-19T09:22:07', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1ba540d5-198f-4b11-ab83-41c2a20312eb' User entered 'No (N)'	System	22 Feb 2021 16:15:28
	System	22 Feb 2021 16:15:28

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-19T09:22:10', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1ba540d5-198f-4b11-ab83-41c2a20312eb' User entered 'No (N)'	System	22 Feb 2021 16:15:28
	System	22 Feb 2021 16:15:28

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-19T09:22:16', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '1ba540d5-198f-4b11-ab83-41c2a20312eb' User entered '19 Feb 2021 09:22:16'	System	22 Feb 2021 16:15:28
	System	22 Feb 2021 16:15:28

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-26T09:22:47-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0c79a3ce-e386-475e-b723-45fe37b2cd9b' User entered 'No (N)'	System	26 Feb 2021 15:23:01
	System	26 Feb 2021 15:23:01

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-26T09:22:51-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0c79a3ce-e386-475e-b723-45fe37b2cd9b' User entered 'No (N)'	System	26 Feb 2021 15:23:01
	System	26 Feb 2021 15:23:01

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-02-26T09:22:57-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '0c79a3ce-e386-475e-b723-45fe37b2cd9b' User entered '26 Feb 2021 15:22:57'	System	26 Feb 2021 15:23:01
	System	26 Feb 2021 15:23:01

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-05T07:53:19-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '81187fb5-670b-4ccd-a0d9-35c33be26735'	System	05 Mar 2021 13:53:33
User entered 'No (N)'	System	05 Mar 2021 13:53:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-05T07:53:23-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '81187fb5-670b-4ccd-a0d9-35c33be26735'	System	05 Mar 2021 13:53:33
User entered 'No (N)'	System	05 Mar 2021 13:53:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-05T07:53:30-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '81187fb5-670b-4ccd-a0d9-35c33be26735' User entered '05 Mar 2021 07:53:30'	System	05 Mar 2021 13:53:33
	System	05 Mar 2021 13:53:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-12T16:17:21-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cef53ee8-104d-4dc2-9ea6-530df2898133'	System	12 Mar 2021 22:17:41
User entered 'No (N)'	System	12 Mar 2021 22:17:41

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-12T16:17:33-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cef53ee8-104d-4dc2-9ea6-530df2898133'	System	12 Mar 2021 22:17:41
User entered 'No (N)'	System	12 Mar 2021 22:17:41

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-12T16:17:37-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'cef53ee8-104d-4dc2-9ea6-530df2898133' User entered '12 Mar 2021 16:17:37'	System	12 Mar 2021 22:17:41
	System	12 Mar 2021 22:17:41

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-19T10:47:04-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5be1313e-a2eb-4751-a46d-bb727a8c7d34' User entered 'No (N)'	System	19 Mar 2021 15:47:16
	System	19 Mar 2021 15:47:16

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-19T10:47:08-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5be1313e-a2eb-4751-a46d-bb727a8c7d34'	System	19 Mar 2021 15:47:16
User entered 'No (N)'	System	19 Mar 2021 15:47:16

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-19T10:47:13-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '5be1313e-a2eb-4751-a46d-bb727a8c7d34' User entered '19 Mar 2021 10:47:13'	System	19 Mar 2021 15:47:16
	System	19 Mar 2021 15:47:16

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-26T10:20:23-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7cebd0a0-b4f6-4b8e-94f9-7ccf8e170ae8'	System	26 Mar 2021 15:20:38
User entered 'No (N)'	System	26 Mar 2021 15:20:38

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-26T10:20:27-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7cebd0a0-b4f6-4b8e-94f9-7ccf8e170ae8' User entered 'No (N)'	System	26 Mar 2021 15:20:38

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-26T10:20:32-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7cebd0a0-b4f6-4b8e-94f9-7ccf8e170ae8' User entered '26 Mar 2021 10:20:32'	System	26 Mar 2021 15:20:38
	System	26 Mar 2021 15:20:38

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-03T09:17:20-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7657f4ce-eb20-4fd2-9b21-02088fd62788' User entered 'No (N)'	System	03 Apr 2021 14:17:31
	System	03 Apr 2021 14:17:31

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-03T09:17:23-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7657f4ce-eb20-4fd2-9b21-02088fd62788'	System	03 Apr 2021 14:17:31
User entered 'No (N)'	System	03 Apr 2021 14:17:31

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-03T09:17:27-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '7657f4ce-eb20-4fd2-9b21-02088fd62788'	System	03 Apr 2021 14:17:31
User entered '03 Apr 2021 09:17:27'	System	03 Apr 2021 14:17:31

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-09T00:38:14-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6a59d666-fa4a-4df5-9883-ace97099a445'	System	09 Apr 2021 05:38:33
User entered 'No (N)'	System	09 Apr 2021 05:38:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-09T00:38:18-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6a59d666-fa4a-4df5-9883-ace97099a445'	System	09 Apr 2021 05:38:33
User entered 'No (N)'	System	09 Apr 2021 05:38:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-09T00:38:28-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '6a59d666-fa4a-4df5-9883-ace97099a445'	System	09 Apr 2021 05:38:33
User entered '09 Apr 2021 00:38:28'	System	09 Apr 2021 05:38:33

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-17T00:16:21-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'eb5972c9-69ad-4795-b0d2-8d3c76b3c467'	System	17 Apr 2021 05:16:43
User entered 'No (N)'	System	17 Apr 2021 05:16:43

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-17T00:16:25-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'eb5972c9-69ad-4795-b0d2-8d3c76b3c467'	System	17 Apr 2021 05:16:43
User entered 'No (N)'	System	17 Apr 2021 05:16:43

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-17T00:16:38-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'eb5972c9-69ad-4795-b0d2-8d3c76b3c467'	System	17 Apr 2021 05:16:43
User entered '17 Apr 2021 00:16:38'	System	17 Apr 2021 05:16:43

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-23T17:08:41-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd535604b-774a-4510-915d-3822d679f54d'	System	23 Apr 2021 22:10:01
User entered 'No (N)'	System	23 Apr 2021 22:10:01

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-23T17:08:46-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd535604b-774a-4510-915d-3822d679f54d'	System	23 Apr 2021 22:10:01
User entered 'No (N)'	System	23 Apr 2021 22:10:01

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-23T17:08:51-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: 'd535604b-774a-4510-915d-3822d679f54d'	System	23 Apr 2021 22:10:01
User entered '23 Apr 2021 17:08:51'	System	23 Apr 2021 22:10:01

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-30T00:56:40-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '62803f14-5e46-4c2b-940f-7d0595317e20' User entered 'No (N)'	System	30 Apr 2021 05:57:08

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

Have you been exposed to someone with 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 (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-30T00:56:44-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '62803f14-5e46-4c2b-940f-7d0595317e20' User entered 'No (N)'	System	30 Apr 2021 05:57:08

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-04-30T00:56:53-05:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '62803f14-5e46-4c2b-940f-7d0595317e20' User entered '30 Apr 2021 00:56:53'	System	30 Apr 2021 05:57:08
	System	30 Apr 2021 05:57:08

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:31:44

US3552191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:31:44
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:31:44

US3552191

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:13:34

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 11:18:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-05T07:53:37-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '27ccf95c-7b60-434b-8131-f9fbb3148486'	System	05 Mar 2021 13:53:44
User entered 'No (N)'	System	05 Mar 2021 13:53:44

US3552191

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:13:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:18:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE20DBCE-368C-45A4-B052-ABA2E570C874)', Time: '2021-03-05T07:53:42-06:00', User OID: 'PatientReportedOutcome (US3552191)', ODM File OID: '27ccf95c-7b60-434b-8131-f9fbb3148486'	System	05 Mar 2021 13:53:44
User entered '05 Mar 2021 07:53:42'	System	05 Mar 2021 13:53:44

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '18 Nov 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:15:05

US3552191

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Dec 2020 16:14:22

US3552191

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 08:54:45
User entered 'l'	System	23 Dec 2020 16:14:22

US3552191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Dec 2020 16:14:34

US3552191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '22 Dec 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Dec 2020 16:14:34

US3552191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Dec 2020 16:14:34

US3552191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	23 Dec 2020 16:14:34

US3552191

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Jan 2021 14:37:46

US3552191

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'l'	System	22 Jan 2021 14:37:46

US3552191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Jan 2021 14:37:58

US3552191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '21 Jan 2021'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Jan 2021 14:37:58

US3552191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Jan 2021 14:37:58

US3552191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Mikayla Frye (b) (4) (b) (4)	22 Jan 2021 14:37:58

US3552191

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	18 Feb 2021 16:59:53

US3552191

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'I'	System	18 Feb 2021 16:59:53

US3552191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:15:49

US3552191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '22 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:15:49

US3552191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:15:49

US3552191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:15:49

US3552191

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:17:00

US3552191

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'I'	System	22 Feb 2021 17:17:00

US3552191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:35

US3552191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered '15 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:35

US3552191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:35

US3552191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'VISIT4'	System	15 Mar 2021 16:14:35

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:24:50
User entered 'Yes (Y)'	(b) (4) Cassandra Zehenny (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:24:50
User entered '15 Mar 2021'	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:24:50
User entered '09:58'	(b) (4) Cassandra Zehenny (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered '15 Mar 2021 09:58'	System	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:24:50
User entered '98.3' F	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:24:50
User entered 'Oral (Oral)'	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:24:50
User entered empty.	(b) (4) Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:24:50
User entered '85'	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'bpm'	System	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User closed query 'Per CDM: Per CCGs, Data is required for respiratory rate. Please review and reconcile. Or else clarify.' (Site from DM).		03 Apr 2021 06:17:50
Query 'Per CDM: Per CCGs, Data is required for respiratory rate. Please review and reconcile. Or else clarify.' answered with 'Please note that "ND" has been entered, indicating that this data was not captured' (Site from DM).	Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:56:10
User opened query 'Per CDM: Per CCGs, Data is required for respiratory rate. Please review and reconcile. Or else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:09:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:24:50
User entered missing code ND - Not Done.	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'breaths/min'	System	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:24:50
User entered '114'	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'mmHg'	System	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:24:50
User entered '75'	Cassandra Zehenny (b) (4) (b) (4)	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'mmHg'	System	30 Mar 2021 14:34:25

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05

US3552191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05

US3552191

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:42

US3552191

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered '15 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:42

US3552191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:52

US3552191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered '15 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:52

US3552191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered '09:09'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:52

US3552191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered '15 Mar 2021 09:09'	System	15 Mar 2021 16:14:52

US3552191

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	15 Mar 2021 16:14:58

US3552191

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:17:05
User entered 'I'	System	15 Mar 2021 16:14:58

US3552191

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[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 15:37:18

US3552191

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

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 15:37:18

US3552191

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[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 15:37:18

US3552191

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:13:34

[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 Dublin (b) (4) (b) (4)	21 Apr 2021 15:37:18

US3552191

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[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 15:37:55

US3552191

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:13:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 15:37:55

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:34

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 12OCT2020 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)	04 Nov 2020 09:41:04
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 12OCT2020 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 13:59:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 12OCT2020 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 07:18:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 2OCT2020 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.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:18:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 and 2OCT2020 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 07:16:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:34

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:34

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '12:39'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:34

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:39
User entered '07 Oct 2020 12:39'	System	18 Nov 2020 21:58:02
User entered '7 Oct 2020 12:39'	System	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:34

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Safety Call (Safety Call)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:13:34

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:45:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 1 (Day 1)'	(b) (4)	
	Mikayla Frye (b) (4)	08 Oct 2020 15:46:06
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '02 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:25
User entered '2 Oct 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:57
User entered '01 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Re-query: Per data entry assessment was not done for day 1-6 and Day 12-13. However, data is present for each symptoms. If confirmed not done please remove all assessment on each symptoms. If confirmed assessment was done consider removing data (check) on the Not done box. Review and update accordingly' (Site from DM). User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) Cassandra Zehenny (b) (4)	18 Jan 2021 11:55:48 15 Jan 2021 21:51:34
Query 'Re-query: Per data entry assessment was not done for day 1-6 and Day 12-13. However, data is present for each symptoms. If confirmed not done please remove all assessment on each symptoms. If confirmed assessment was done consider removing data (check) on the Not done box. Review and update accordingly' answered with 'updated' (Site from DM). User opened query 'Re-query: Per data entry assessment was not done for day 1-6 and Day 12-13. However, data is present for each symptoms. If confirmed not done please remove all assessment on each symptoms. If confirmed assessment was done consider removing data (check) on the Not done box. Review and update accordingly' (Site from DM). Query 'Re-query: Per data entry assessment was not done for day 1 to Day 10. However, data is present for each symptoms. If confirmed not done please remove all assessment on each symptoms. If confirmed assessment was done consider removing data (check) on the Not done box. Review and update accordingly. ' canceled (Site from DM). User opened query 'Re-query: Per data entry assessment was not done for day 1 to Day 10. However, data is present for each symptoms. If confirmed not done please remove all assessment on each symptoms. If confirmed assessment was done consider removing data (check) on the Not done box. Review and update accordingly. ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6)	15 Jan 2021 21:51:30 14 Jan 2021 09:19:39 14 Jan 2021 09:19:12 14 Jan 2021 09:17:25

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please check from log lines 1-6 and 12-13. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 09:17:25
Query 'Per CDM: Please check from log lines 1-6 and 12-13. 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 19:59:12
User opened query 'Per CDM: Please check from log lines 1-6 and 12-13. 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 13:30:28
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:06

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 2 (Day 2)'	(b) (4)	
	Mikayla Frye (b) (4)	08 Oct 2020 15:46:48
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '03 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:53:02
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:46:48

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 3 (Day 3)'	(b) (4)	
	Mikayla Frye (b) (4)	08 Oct 2020 15:47:31
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '04 Oct 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:53:28
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	08 Oct 2020 15:47:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:47:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 5 (Day 5)'	(b) (4)	
	Mikayla Frye (b) (4)	08 Oct 2020 15:48:20
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '05 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:25
User entered '5 Oct 2020' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33
User entered '4 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:53:38
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:48:20

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 5 (Day 5)'	(b) (4)	
	Mikayla Frye (b) (4)	08 Oct 2020 15:49:03
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:25
User entered '6 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:53:56
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 6 (Day 6)'	(b) (4)	
	Mikayla Frye (b) (4)	08 Oct 2020 15:49:29
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '07 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:25
User entered '7 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:53:56
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31
User entered '0'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:49:29

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 8 (Day 8)'	(b) (4)	
	Mikayla Frye (b) (4)	08 Oct 2020 15:51:54
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:25
User entered '8 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '0'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '94'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	08 Oct 2020 15:51:54

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '98.3' F	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	08 Oct 2020 15:51:54

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 9 (Day 9)'	(b) (4)	
	Heather Douds (b) (4)	09 Oct 2020 14:02:31
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:25
User entered '9 Oct 2020'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '95'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '99' F	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:02:31

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 10 (Day 10)'	(b) (4)	
	Stanley Dublin (b) (4)	12 Oct 2020 15:37:38
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '10 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Days 9 and 10 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:46:44
Query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Days 9 and 10 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' answered with 'Not COVID positive. ' (Site from DM).	Cassandra Zehenny (b) (4)	05 Nov 2020 15:40:59
User opened query 'Per CDM: it appears subject as </= 93% saturation recorded in Symptom Log Days 9 and 10 yet there is no Covid Severity Assessment form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 20:10:25
User entered '88'	Stanley Doublin (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '98' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:37:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 11 (Day 11)'	(b) (4)	
	Stanley Dublin (b) (4)	12 Oct 2020 15:39:08
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '11 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '91'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '97.8' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:08

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:22:11
User entered 'Day 12 (Day 12)'	(b) (4) Stanley Doublin (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '12 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '95'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '98.5' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 15:39:56

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 1 (Day 1)' reason for change:	(b) (4)	
Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered 'Day 16 (Day 16)'	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 17:25:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 17:25:21
User entered '30 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 17:22:11
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '0' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Jan 2021 21:53:56
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered '0'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	28 Oct 2020 17:25:21
User entered empty.	System	28 Oct 2020 17:22:11

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:25:21
User entered empty.	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:25:21
User entered empty.	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:22:11

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Day 2 (Day 2)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	18 Nov 2020 21:58:25
User entered '1 Oct 2020'	Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '0' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	15 Jan 2021 21:53:56
User entered '1'	(b) (4)	
	Heather Douds (b) (4)	28 Oct 2020 17:26:33
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User entered '%'	System	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered missing code ND - Not Done.	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Mild (Mild)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:13:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'None (None)'	(b) (4) Heather Douds (b) (4) (b) (4)	28 Oct 2020 17:26:33

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '8 Oct 2020'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[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 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	09 Oct 2020 14:01:03

US3552191

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

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 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Oct 2020 17:45:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 17:45:41
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Oct 2020 17:45:41
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 14:01:03
User entered empty.	Heather Douds (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '8 Oct 2020'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[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 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	09 Oct 2020 14:01:03

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:13:34

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:12:51
User entered '0'	System	09 Oct 2020 17:45:41

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:13:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:13:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Nov 2020 15:22:46
User entered '9 Oct 2020'	(b) (4)	
	Stanley Dublin (b) (4)	29 Oct 2020 18:21:36
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:13:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:13:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '12 Oct 2020'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:13:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:13:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:13:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:13:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:13:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Stanley Dublin (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:13:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:13:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:13:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:13:34

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Stanley Dublin (b) (4)	29 Oct 2020 18:21:36

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:13:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:21:36

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 15:22:16
User entered '8 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[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 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Home (Home)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User entered 'SICKD1'	System	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon trey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'resolved' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:17:33
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'resolved' (Site from DM).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:24:09
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:06:36
User entered '8 Oct 2020'	Stanley Doublin (b) (4)	29 Oct 2020 18:16:00
	(b) (4)	

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '08:30'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User entered '08 Oct 2020 08:30'	System	09 Nov 2020 15:23:58
User entered '8 Oct 2020 08:30'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Per CDM: As per CCG: Data is required, please review and update accordingly. ' (Site from DM).	(b) (4)	
Query 'Per CDM: As per CCG: Data is required, please review and update accordingly. ' answered with 'Unable to be done at time of visit, data unavailable' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:25:58
User opened query 'Per CDM: As per CCG: Data is required, please review and update accordingly. ' (Site from DM).	Cassandra Zehenny (b) (4)	09 Nov 2020 15:24:02
User entered missing code ND - Not Done.	(b) (4)	
DataPoint set to visible.	(b) (4), (b) (6)	09 Nov 2020 04:06:04
	Stanley Doublin (b) (4)	29 Oct 2020 18:16:00
	(b) (4)	
	System	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User closed query 'Per CDM: As per CCG: Data is required, please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:25:56
Query 'Per CDM: As per CCG: Data is required, please review and update accordingly.' answered with 'Unable to be done at time of visit, data unavailable' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 15:24:05
User opened query 'Per CDM: As per CCG: Data is required, please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:06:14
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00
DataPoint set to visible.	System	29 Oct 2020 18:15:21

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '98.3' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '111'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User entered 'bpm'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '20'	(b) (4) Stanley Doublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User entered 'breaths/min'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '128'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User entered 'mmHg'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '80'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User entered 'mmHg'	System	29 Oct 2020 18:16:00

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39

US3552191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:13:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39

US3552191

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:49

US3552191

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:13:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:16:49

US3552191

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:13:34

[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 18:52:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:17:18

US3552191

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:13:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:52:39
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	10 Nov 2020 15:22:39
User entered '8 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:17:43
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Oct 2020 18:17:18

US3552191

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:09:54

US3552191

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '13 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:09:54

US3552191

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[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 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:09:54

US3552191

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

Form: Visit Date

Generated On: 10 Jun 2021 08:13:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 20:09:54

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '13 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:07

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[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 19:59:47
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:41:43

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:07

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:41:43

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '13 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:07

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Stanley Doublin (b) (4)	13 Jan 2021 20:10:07

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:02:29
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Dublin (b) (4)	13 Jan 2021 20:10:07
	(b) (4)	

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:02:29
User entered 'mRNA-1273 (mRNA-1273)'	Stanley Dublin (b) (4)	13 Jan 2021 20:10:07
	(b) (4)	

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	13 Jan 2021 20:10:07

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User entered empty.	System	13 Jan 2021 20:10:07

US3552191

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

Form: Unblinding

Generated On: 10 Jun 2021 08:13:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User entered empty.	System	13 Jan 2021 20:10:07

US3552191

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:19

US3552191

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '13 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:19

US3552191

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '12:01'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:19

US3552191

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:13:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User entered '13 Jan 2021 12:01'	System	13 Jan 2021 20:10:19

US3552191

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:28

US3552191

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '13 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:28

US3552191

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '12:04'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:10:28

US3552191

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:13:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:47
User entered '13 Jan 2021 12:04'	System	13 Jan 2021 20:10:28

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:13:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:48:42
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:26:02

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:25:52
Query 'Patient reported elevated hemoglobin on 06Oct. Please consider capturing this as an AE. ' canceled (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 14:25:05
User opened query 'Patient reported elevated hemoglobin on 06Oct. Please consider capturing this as an AE. ' (Site from CRA).		15 Oct 2020 14:13:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:27:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 17:27:52
Data point term sent to Coder	System	02 Oct 2020 17:27:21
User entered 'fatigue'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:25:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:25:53
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:25:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:25:55
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:25:56
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:25:56
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:25:58
User entered '24 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:00
	(b) (4), (b) (6)	
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 17:30:50
User entered '18:42' reason for change: Data Entry Error	Stanley Dublin (b) (4)	02 Oct 2020 17:30:50
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 17:27:13
User entered empty.	Stanley Dublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User entered '24 Sep 2020 18:42'	System	02 Oct 2020 17:30:50
User entered empty.	System	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:33
DataPoint Verified.	(b) (4)	12 Apr 2021 17:55:48
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:48
Signature has been broken.	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:18
User entered 'No (N)' reason for change: New Information	(b) (4)	09 Apr 2021 18:09:18
User signature succeeded.	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:18
DataPoint Verified.	(b) (4)	23 Mar 2021 15:29:15
DataPoint Un-verified.	(b) (4), (b) (6)	23 Mar 2021 15:29:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 18:52:30
DataPoint Verified.	Joan Siegner (b) (4)	13 Nov 2020 18:52:30
User entered 'No (N)'	(b) (4)	11 Nov 2020 17:31:42
	(b) (4)	11 Nov 2020 17:31:42
	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
	(b) (4)	09 Nov 2020 17:26:02
	(b) (4), (b) (6)	09 Nov 2020 17:26:02
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 17:55:50
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:18
	(b) (4)	
Signature has been broken.	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:18
	(b) (4)	
User entered '01 Feb 2021' reason for change: New Information	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:18
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
DataPoint Un-verified.	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:03
User entered '30 Sep 2020'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	12 Apr 2021 11:53:58
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:30
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Apr 2021 18:09:18
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Nov 2020 17:31:42
DataPoint Verified.	System	11 Nov 2020 17:31:42
	(b) (4), (b) (6)	09 Nov 2020 17:26:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Oct 2020 11:35:37
Query 'Data is required. Please provide.' answered with 'exact time is unknown' (Site from System).	Stanley Doublin (b) (4)	02 Oct 2020 17:30:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 17:30:46
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 17:27:13
User entered empty.	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User entered empty.	System	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:26:06
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:08
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:26:08
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:10
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:10
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:11
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:11
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:13
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:13
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:26:15
User entered empty.	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:17
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:26:17
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:18
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:26:18
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:20
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:22
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:22
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:24
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:24
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:25
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:25
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:26:27
User entered 'Related (RELATED)'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:26:28
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:50:14
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:39:19
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Dublin (b) (4)	23 Nov 2020 17:39:19
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:30
User entered 'None (NONE)'	Stanley Dublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:32
User entered 'l'	(b) (4), (b) (6)	09 Nov 2020 17:26:32
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:33
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:33
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:35
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:26:35
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:33
DataPoint Verified.	(b) (4)	12 Apr 2021 17:55:54
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 17:55:54
Signature has been broken.	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	09 Apr 2021 18:09:18
User signature succeeded.	Cassandra Zehenny (b) (4)	09 Apr 2021 18:09:18
DataPoint Verified.	(b) (4)	23 Mar 2021 15:29:15
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Joan Siegner (b) (4)	11 Nov 2020 17:31:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

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 23:19:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:26:38
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:26:39
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:26:39
	Stanley Doublin (b) (4)	02 Oct 2020 17:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User entered '0'	System	02 Oct 2020 17:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20
User entered '0'	System	02 Oct 2020 17:27:13

US3552191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:20

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #7 (SORE THROAT), 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)	18 Jan 2021 04:54:42
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #7 (SORE THROAT), 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 'no overarching diagnosis to combine this under' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:47:38
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #7 (SORE THROAT), 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)	14 Jan 2021 05:54:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:06
DataPoint Un-verified.		09 Nov 2020 17:39:13
DataPoint Verified.		09 Nov 2020 17:38:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 19:25:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 19:25:22
Data point term sent to Coder	System	09 Oct 2020 19:24:46
User entered 'cough'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:45:15
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:39:11
DataPoint Verified.		09 Nov 2020 17:38:15
User entered 'No (N)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:45:13
User entered 'No (N)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	09 Nov 2020 17:45:11
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:45:11
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:45:08
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:03
	(b) (4)	
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User entered empty.	System	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:03
	(b) (4)	
User entered '8 Oct 2020'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User entered empty.	System	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:50:33
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:50:33
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:41:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:41:13
reason for change: Data Entry Error	Stanley Doublin (b) (4)	23 Nov 2020 17:41:13
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'l'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User entered '0'	System	09 Oct 2020 19:24:10

US3552191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29
User entered '0'	System	09 Oct 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:11
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 19:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 19:26:28
Data point term sent to Coder	System	09 Oct 2020 19:25:47
User entered 'headache'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:13:13
User entered 'No (N)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:14
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:16
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:16
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:13:17
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:16
User entered '8 Oct 2020'	(b) (4)	
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:20
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:13:20
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User entered empty.	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:21
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:21
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:23
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 15:28:16
User entered '8 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User entered empty.	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:50:41
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:50:41
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:41:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:41:21
reason for change: Data Entry Error	Stanley Doublin (b) (4)	23 Nov 2020 17:41:21
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'l'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:24:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:24:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User entered '0'	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30
User entered '0'	System	09 Oct 2020 19:24:50

US3552191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:30

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:13:29
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) (b) (4)	09 Oct 2020 19:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:26:28
Data point term sent to Coder	System	09 Oct 2020 19:25:52
User entered 'sore throat'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:13:32
User entered 'No (N)'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:34
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:13:35
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:26
User entered '8 Oct 2020'	(b) (4)	
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:37
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:13:37
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User entered empty.	System	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:13:38
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:38
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:13:40
User entered '08 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:28:26
User entered '8 Oct 2020'	(b) (4)	
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User entered empty.	System	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:50:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:50:47
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:41:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:41:32
reason for change: Data Entry Error	Stanley Doublin (b) (4)	23 Nov 2020 17:41:32
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'l'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4) (b) (4)	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	09 Oct 2020 19:25:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User entered '0'	System	09 Oct 2020 19:25:25

US3552191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35
User entered '0'	System	09 Oct 2020 19:25:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:05
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)	14 Oct 2020 15:30:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:30:27
Data point term sent to Coder	System	14 Oct 2020 15:29:10
User entered 'Anemia'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:14:06
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:28:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 15:28:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Oct 2020 15:28:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:28:47
User entered empty.	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:08
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:14:10
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:14:10
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:12
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:29:11
User entered '9 Oct 2020'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User entered empty.	System	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:51:21
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:21
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:16:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:16:16
DataPoint Verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:16:16
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:51:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:24
	Stanley Doublin (b) (4)	19 Nov 2020 13:16:16
User entered '20 Oct 2020' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:16:16
DataPoint Verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:16:16
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User entered empty.	System	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:51:31
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Dec 2020 17:06:38
	(b) (4)	
User entered 'Related (RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	28 Dec 2020 17:06:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:51:29
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:29
DataPoint Un-verified.	Stanley Dublin (b) (4)	23 Nov 2020 17:41:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:41:47
reason for change: Data Entry Error	Stanley Dublin (b) (4)	23 Nov 2020 17:41:47
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'l'	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:51:27
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:27
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:16:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	19 Nov 2020 13:16:16
Data Entry Error	Stanley Doublin (b) (4)	19 Nov 2020 13:16:16
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Mikayla Frye (b) (4)	14 Oct 2020 15:28:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User entered '0'	System	14 Oct 2020 15:28:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41
User entered 'I'	System	14 Oct 2020 15:28:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:41

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:20
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 12:28:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 12:28:06
User closed query 'Per DM CLR: Please specify the type (e.g., Sinus Tachycardia, Ventricular Tachycardia, etc) of TACHYCARDIA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	05 Nov 2020 04:17:59
' (Site from DM).		
Data point term sent to Coder	System	02 Nov 2020 20:44:00
Query 'Per DM CLR: Please specify the type (e.g., Sinus Tachycardia, Ventricular Tachycardia, etc) of TACHYCARDIA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 20:43:42
' answered with 'updated' (Site from DM).		
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 20:43:38
User entered 'SINUS TACHYCARDIA' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	02 Nov 2020 20:43:38
User opened query 'Per DM CLR: Please specify the type (e.g., Sinus Tachycardia, Ventricular Tachycardia, etc) of TACHYCARDIA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	02 Nov 2020 11:45:03
' (Site from DM).		
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:10:29

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Oct 2020 16:10:29
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 16:09:28
User entered 'Tachycardia'	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:14:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:14:22
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:14:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:14:23
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:14:24
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:14:24
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 18:14:26
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:29:22
User entered '9 Oct 2020'	(b) (4)	
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User entered empty.	System	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	23 Nov 2020 16:18:47
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:18:47
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:17:14
DataPoint Verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	23 Nov 2020 16:18:53
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 16:18:53
	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:17:14
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User entered empty.	System	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Douds (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

US3552191

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Doubs (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 20:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'Related (RELATED)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 16:09:20
User entered empty.	System	15 Oct 2020 16:09:20
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Oct 2020 16:09:20
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:51:39
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:39
DataPoint Un-verified.	Stanley Doublin (b) (4)	23 Nov 2020 17:41:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	23 Nov 2020 17:41:58
reason for change: Data Entry Error	Stanley Doublin (b) (4)	23 Nov 2020 17:41:58
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 18:52:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'None (NONE)' reason for change: Data Entry Error	System	15 Oct 2020 20:10:11
User opened query 'Data is required. Please complete.' (Site from System).	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
User entered empty.	(b) (4)	15 Oct 2020 20:10:11
	System	15 Oct 2020 16:09:20
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:49
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#12 & 14) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).		03 Dec 2020 05:16:56
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#12 & 14) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Dec 2020 16:28:42
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	01 Dec 2020 16:28:37
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	01 Dec 2020 16:28:37
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#12 & 14) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 05:14:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 20:10:11
User entered '1' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	15 Oct 2020 20:10:11
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 16:09:20
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:51:47
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	01 Dec 2020 16:28:37
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	01 Dec 2020 16:28:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Heather Douds (b) (4) (b) (4)	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:45
	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	19 Nov 2020 13:17:14
Data Entry Error	Stanley Doublin (b) (4)	19 Nov 2020 13:17:14
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 20:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 20:10:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Mikayla Frye (b) (4)	15 Oct 2020 20:10:11
Data Entry Error	(b) (4)	15 Oct 2020 20:10:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 16:09:20
User entered empty.	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	15 Oct 2020 16:09:20

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Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	13 Nov 2020 18:52:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	Heather Douds (b) (4)	15 Oct 2020 16:09:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User entered '0'	System	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43
User entered 'I'	System	15 Oct 2020 16:09:20

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:43

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Muscle weakness - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 20:50:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 20:50:36
Data point term sent to Coder	System	20 Oct 2020 20:49:31
User entered 'Muscle Weakness'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:04
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:17:06
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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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)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:17:07
User entered 'No (N)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	11 Nov 2020 18:14:35
Query 'Per source, muscle weakness start date 19Oct. Please reconcile, ' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:14:34
User opened query 'Per source, muscle weakness start date 19Oct. Please reconcile, ' (Site from CRA).		11 Nov 2020 16:17:46
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:29:32
User entered '9 Oct 2020'	(b) (4)	
	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User entered empty.	System	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:52:13
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:13
	Mikayla Frye (b) (4)	22 Jan 2021 14:40:03
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Mikayla Frye (b) (4)	22 Jan 2021 14:40:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:52:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:15
	Mikayla Frye (b) (4)	22 Jan 2021 14:40:03
	(b) (4)	
User entered '22 Dec 2020' reason for change: New Information	Mikayla Frye (b) (4)	22 Jan 2021 14:40:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User entered empty.	System	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Related (RELATED)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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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)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Applicable (NOT APPLICABLE)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'l'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Form: Adverse Events (11)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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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)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:52:21
DataPoint Un-verified.	Mikayla Frye (b) (4)	22 Jan 2021 14:40:03
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mikayla Frye (b) (4)	22 Jan 2021 14:40:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	20 Oct 2020 20:48:53

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Cassandra Zehenny (b) (4)	20 Oct 2020 20:48:53
	(b) (4)	

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User entered '0'	System	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:13:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51
User entered 'I'	System	20 Oct 2020 20:48:53

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Folder: Adverse Events

Form: Adverse Events (11)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:51

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Folder: Adverse Events

Form: Adverse Events (12)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:24:38
DataPoint Verified.		20 Jan 2021 14:22:21
User entered	System	06 Jan 2021 14:46:38
'USA-US089-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	06 Jan 2021 14:46:38

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Folder: Adverse Events

Form: Adverse Events (12)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:19
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Basedow's disease, LLT: Graves' disease - version MedDRA\23.0.	Coder Import (b) (4)	30 Nov 2020 15:55:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Nov 2020 15:55:05
Data point term sent to Coder	System	30 Nov 2020 15:53:42
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:53:13
	(b) (4)	
Coding entries removed.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:53:13
	(b) (4)	
User entered 'Graves' Disease' reason for change: New Information	Cassandra Zehenny (b) (4)	30 Nov 2020 15:53:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:31
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\23.0.	Coder Import (b) (4)	27 Oct 2020 17:27:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Oct 2020 17:27:04
Data point term sent to Coder	System	27 Oct 2020 17:21:06
User entered 'hyperthyroidism'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:16:33
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:16:35
User entered 'No (N)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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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)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:16:37
User entered 'No (N)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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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)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:23
DataPoint Un-verified.	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
User entered '30 Sep 2020' reason for change: New Information	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:49
User entered '26 Oct 2020'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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Folder: Adverse Events

Form: Adverse Events (12)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:20:45

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:04:34
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	15 Mar 2021 16:57:04
DataPoint Un-verified.	System	15 Mar 2021 16:57:04
	Heather Douds (b) (4)	15 Mar 2021 16:57:04
User entered 'No (N)' reason for change: New Information	(b) (4)	15 Mar 2021 16:57:04
	Heather Douds (b) (4)	15 Mar 2021 16:57:04
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	15 Mar 2021 16:56:39
DataPoint Verified.	System	15 Mar 2021 16:56:39
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Yes (Y)'	(b) (4)	13 Nov 2020 18:52:30
	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:04:36
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
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. Please leave query open until end date is achieved or subject reaches a new baseline. ' (Site from Safety).	(b) (4)	(b) (4), (b) (6)
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. Please leave query open until end date is achieved or subject reaches a new baseline. ' answered with 'Resolved with sequelae' (Site from Safety).	Heather Douds (b) (4)	15 Mar 2021 16:56:50
DataPoint Un-verified.	(b) (4)	15 Mar 2021 16:56:39
User entered '1 Feb 2021' reason for change: New Information	Heather Douds (b) (4)	15 Mar 2021 16:56:39
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. Please leave query open until end date is achieved or subject reaches a new baseline. ' (Site from Safety).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 17:20:45

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:26
DataPoint Un-verified.	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change:	Heather Douds (b) (4)	07 Jan 2021 20:01:43
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	20 Jan 2021 14:22:28
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).	(b) (4), (b) (6)	05 Jan 2021 22:04:33
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	05 Jan 2021 21:50:05
DataPoint Un-verified.	Heather Douds (b) (4)	05 Jan 2021 21:50:05
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	05 Jan 2021 21:50:05
DataPoint Verified.	Heather Douds (b) (4)	13 Nov 2020 18:52:30
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 17:20:45
	Joan Siegner (b) (4)	

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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Form: Adverse Events (12)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	20 Jan 2021 14:22:33
User closed query 'Requires inpatient or prolongation System 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)	07 Jan 2021 20:03:16
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		07 Jan 2021 20:03:16
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	07 Jan 2021 20:01:43
DataPoint Un-verified.	Heather Douds (b) (4)	07 Jan 2021 20:01:43
User entered '1' reason for change: New Information	(b) (4)	07 Jan 2021 20:01:43
DataPoint Verified.	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:34
DataPoint Un-verified.	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
User entered '09 Oct 2020' reason for change: New Information	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	(b) (4)	
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:36
DataPoint Un-verified.	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
User entered '10 Oct 2020' reason for change: New Information	Heather Douds (b) (4)	07 Jan 2021 20:01:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:38
DataPoint Un-verified.	Heather Douds (b) (4)	07 Jan 2021 20:03:16
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	07 Jan 2021 20:03:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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Form: Adverse Events (12)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:40
DataPoint Un-verified.	Heather Douds (b) (4)	05 Jan 2021 22:04:33
	(b) (4)	
User entered '1' reason for change: New Information	Heather Douds (b) (4)	05 Jan 2021 22:04:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:43
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Dec 2020 17:06:15
	(b) (4)	
User entered 'Related (RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4)	28 Dec 2020 17:06:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Related (NOT RELATED)'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'Not Applicable (NOT APPLICABLE)'	Joan Siegner (b) (4) [REDACTED]	27 Oct 2020 17:20:45

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None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered 'l'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:22:47
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).		18 Jan 2021 11:47:31
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 21:48:17
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	15 Jan 2021 21:47:59
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	15 Jan 2021 21:47:59
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:53:58
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered '0'	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:04:40
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
User closed 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)	16 Mar 2021 16:24:33
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Heather Douds (b) (4) (b) (4)	15 Mar 2021 16:58:19
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	15 Mar 2021 16:56:39
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	15 Mar 2021 16:56:39
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)	16 Jan 2021 15:28:28
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 17:20:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 17:20:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	27 Oct 2020 17:20:53
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 17:20:45
User entered empty.	Joan Siegner (b) (4) (b) (4)	27 Oct 2020 17:20:45

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:04:48
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 16:58:12
DataPoint Un-verified.	System	15 Mar 2021 16:58:12
	Heather Douds (b) (4)	15 Mar 2021 16:58:12
	(b) (4)	
User entered 'Per notes from physician's PE today at clinic, subject has reached new baseline, has ongoing fatigue and needs medications (see con meds)'	Heather Douds (b) (4)	15 Mar 2021 16:58:12
reason for change: New Information	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Mar 2021 16:56:39
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4)	27 Oct 2020 17:20:45

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:04:50
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	15 Mar 2021 16:56:39
User entered 'SUBJECT HAS PREVIOUSLY REPORTED ADVERSE EVENTS OF PERIPHERAL EDEMA AND SHORTNESS OF BREATH (WITH THE FOLLOWING DETAILS: SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"; PCP PRESCRIBED ATENOLOL FOR SUBJECT, STARTED ON 30OCT2020. AS OF 11/18 PHONE CALL, SUBJECT REPORTS THAT PERIPHERAL EDEMA HAS RESOLVED, SOB IS ONGOING) ARE RETROSPECTIVELY, CONSISTENT WITH HYPERTHYROIDISM. AES OF ANEMIA, SINUS TACHYCARDIA, & MUSCLE WEAKNESS ARE ALSO RELATED TO THIS DIAGNOSIS PER PI. Per PE today at clinic (3/15), subject has reached new baseline; has ongoing fatigue and need for medications.' reason for change: New Information	Heather Douds (b) (4)	15 Mar 2021 16:56:39

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EAB) (1725)

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Form: Adverse Events (12)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR RQ: Please review SAE Narrative = HAD ECHOCARDIOGRAM THE AM OF 12OCT2020T. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate and note that in Con Procedure ecrf there is an option to indicate that procedures ar diagnostic in nature. Else, re-clarify ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:14:41
User closed query 'Per DM CLR RQ: Please review narrative = HAD LAB WORK, ECG AND CT OF CHEST. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate and note that in Con Procedure ecrf there is an option to indicate that procedures ar diagnostic in nature. Else, re-clarify. ' (Site from DM).		24 Feb 2021 12:14:39
Query 'Per DM CLR RQ: Please review SAE Narrative = HAD ECHOCARDIOGRAM THE AM OF 12OCT2020T. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate and note that in Con Procedure ecrf there is an option to indicate that procedures ar diagnostic in nature. Else, re-clarify ' answered with 'this is non-invasive and therefore not considered a procedure. ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 22 Feb 2021 20:39:52
Query 'Per DM CLR RQ: Please review narrative = HAD LAB WORK, ECG AND CT OF CHEST. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate and note that in Con Procedure ecrf there is an option to indicate that procedures ar diagnostic in nature. Else, re-clarify. ' answered with 'These are not considered con procedures as they are non-invasive. we will not be including them on the con procedure list. thank you. ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 22 Feb 2021 20:39:35

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR RQ: Please review SAE Narrative = HAD ECHOCARDIOGRAM THE AM OF 12OCT2020T. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate and note that in Con Procedure ecrf there is an option to indicate that procedures ar diagnostic in nature. Else, re-clarify ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:15:35
User opened query 'Per DM CLR RQ: Please review narrative = HAD LAB WORK, ECG AND CT OF CHEST. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate and note that in Con Procedure ecrf there is an option to indicate that procedures ar diagnostic in nature. Else, re-clarify. ' (Site from DM).		22 Feb 2021 12:13:28
Query '□ Per DM CLR-RQ: Response noted. Please note in the Con procedure ecrf there is an option to indicate that procedures are diagnostic in nature, please review and capture diagnostic tests as appropriate.' canceled (Site from DM).		22 Feb 2021 12:13:19
Query 'Per DM CLR-RQ: Response noted. Please note in the Con procedure ecrf there is an option to indicate that procedures are diagnostic in nature, please review and capture diagnostic tests as appropriate.' canceled (Site from DM).		22 Feb 2021 12:13:16
User opened query '□ Per DM CLR-RQ: Response noted. Please note in the Con procedure ecrf there is an option to indicate that procedures are diagnostic in nature, please review and capture diagnostic tests as appropriate.' (Site from DM).		22 Feb 2021 12:11:35
User closed query 'Per DM CLR RQ: Please review narrative = HAD LAB WORK, ECG AND CT OF CHEST. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate. Else, clarify' (Site from DM).		22 Feb 2021 12:11:35

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Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. Please note in the Con procedure ecrf there is an option to indicate that procedures are diagnostic in nature, please review and capture diagnostic tests as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:10:53
User closed query 'Per DM CLR: SAE Narrative = HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		22 Feb 2021 12:10:53
User closed query 'Per DM CLR: SAE Narrative = X RAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		19 Feb 2021 09:38:55
Query 'Per DM CLR RQ: Please review narrative = HAD LAB WORK, ECG AND CT OF CHEST. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate. Else, clarify' answered with 'These are not procedures. Please stop querying us about this.' (Site from DM).	Cassandra Zehenny (b) (4)	02 Feb 2021 22:33:46
User opened query 'Per DM CLR RQ: Please review narrative = HAD LAB WORK, ECG AND CT OF CHEST. These Diagnostic Procedures are not captured in Con Proc eCRF. Review and update entries as appropriate. Else, clarify' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 08:44:23
User closed query 'Per DM CLR: SAE Narrative = HAD LAB WORK, ECG AND CT OF CHEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		02 Feb 2021 08:44:23
Query 'Per DM CLR: SAE Narrative = X RAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'These are not invasive and therefore not procedure. Simply diagnostic tests' (Site from DM).	Cassandra Zehenny (b) (4)	27 Jan 2021 17:54:54

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'These are not invasive and therefore not procedure. Simply diagnostic tests' (Site from DM).	Cassandra Zehenny (b) (4)	27 Jan 2021 17:54:52
Query 'Per DM CLR: SAE Narrative = HAD LAB WORK, ECG AND CT OF CHEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'These are not invasive and therefore not procedure. Simply diagnostic tests' (Site from DM).	Cassandra Zehenny (b) (4)	27 Jan 2021 17:54:49
User opened query 'Per DM CLR: SAE Narrative = X RAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 23:31:51
User opened query 'Per DM CLR: SAE Narrative = HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		26 Jan 2021 23:31:45
User opened query 'Per DM CLR: SAE Narrative = HAD LAB WORK, ECG AND CT OF CHEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		26 Jan 2021 23:31:39
User closed query 'PV Query: Please confirm when the subject began to experience any symptoms (e.g. tachycardia, palpitations, short of breath, fatigue, edema in extremities, muscle weakness, eye symptoms) relevant to hyperthyroidism prior to mRNA-1273 administration. If the subject did not experience symptoms prior to start of study drug, please confirm in your response.' (Site from Safety).		20 Jan 2021 15:42:28
DataPoint Verified.		20 Jan 2021 14:22:53

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm when the subject began to experience any symptoms (e.g. tachycardia, palpitations, short of breath, fatigue, edema in extremities, muscle weakness, eye symptoms) relevant to hyperthyroidism prior to mRNA-1273 administration. If the subject did not experience symptoms prior to start of study drug, please confirm in your response.' answered with 'first symptom noted by subject and reported to site was SOB on 07OCT per narrative' (Site from Safety).	Heather Douds (b) (4)	19 Jan 2021 19:15:55
User opened query 'PV Query: Please confirm when the subject began to experience any symptoms (e.g. tachycardia, palpitations, short of breath, fatigue, edema in extremities, muscle weakness, eye symptoms) relevant to hyperthyroidism prior to mRNA-1273 administration. If the subject did not experience symptoms prior to start of study drug, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Jan 2021 15:28:49

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Form: Adverse Events (12)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS PREVIOUSLY REPORTED ADVERSE EVENTS OF PERIPHERAL EDEMA AND SHORTNESS OF BREATH (WITH THE FOLLOWING DETAILS: SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"; PCP PRESCRIBED ATENOLOL FOR SUBJECT, STARTED ON 30OCT2020. AS OF 11/18 PHONE CALL, SUBJECT REPORTS THAT PERIPHERAL EDEMA HAS RESOLVED, SOB IS ONGOING) ARE RETROSPECTIVELY, CONSISTENT WITH HYPERTHYROIDISM. AES OF ANEMIA, SINUS TACHYCARDIA, & MUSCLE WEAKNESS ARE ALSO RELATED TO THIS DIAGNOSIS PER PI.'	Heather Douds (b) (4) (b) (4)	07 Jan 2021 20:03:50

reason for change: New Information

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Folder: Adverse Events

Form: Adverse Events (12)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS PREVIOUSLY REPORTED ADVERSE EVENTS OF PERIPHERAL EDEMA AND SHORTNESS OF BREATH (WITH THE FOLLOWING DETAILS: SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"; PCP PRESCRIBED ATENOLOL FOR SUBJECT, STARTED ON 30OCT2020. AS OF 11/18 PHONE CALL, SUBJECT REPORTS THAT PERIPHERAL EDEMA HAS RESOLVED, SOB IS ONGOING) ARE RETROSPECTIVELY, CONSISTENT WITH HYPERTHYROIDISM. WE ARE TRYING TO CONTACT THE ENDOCRINOLOGY DIVISION AT THE VA FOR FURTHER CLARIFICATION. AES of anemia, sinus tachycardia, & muscle weakness ARE ALSO RELATED TO THIS DIAGNOSIS PER PI.' reason for change: New Information	Heather Douds (b) (4)	07 Jan 2021 20:03:02

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:13:34

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS PREVIOUSLY REPORTED ADVERSE EVENTS OF PERIPHERAL EDEMA AND SHORTNESS OF BREATH (with the following details: SUBJECT NOTIFIED SITE 07OCT2020 OF SHORTNESS OF BREATH ON EXERTION, FATIGUE AND SWOLLEN ANKLES. SITE SENT HOME HEALTH NURSES TO HER HOME ON 08OCT2020 TO DO ILLNESS VISIT AND ADVISED HER TO NOTIFY HER PCP OF SYMPTOMS. SUBJECT SAW PCP ON 09OCT2020 AND WAS SENT TO ER FOR CARDIAC EVALUATION. WAS ADMITTED OVERNIGHT TO HOSPITAL AND TREATED WITH IVP LASIX AND DIURESED. HAD LAB WORK, ECG AND CT OF CHEST. DISCHARGED THE NEXT DAY AND HAD ECHOCARDIOGRAM THE AM OF 12OCT2020. HOSPITAL MEDICAL RECORDS RECEIVED AND SENT TO SPONSOR. PER CARDIOLOGIST'S OFFICE, ECHO NEGATIVE. X RAY "WITHOUT SIGNIFICANT OR ACUTE FINDINGS," CHEST CT "NO EVIDENCE OF PE," ECG "SINUS TACHYCARDIA, NO EVIDENCE OF INJURY PATTERN"; PCP PRESCRIBED ATENOLOL FOR SUBJECT, STARTED ON 30OCT2020. AS OF 11/18 PHONE CALL, SUBJECT REPORTS THAT peripheral edema HAS RESOLVED, SOB is ongoing) ARE RETROSPECTIVELY, CONSISTENT WITH HYPERTHYROIDISM. WE ARE TRYING TO CONTACT THE ENDOCRINOLOGY DIVISION AT THE VA FOR FURTHER CLARIFICATION. AES NUMBER 8, 9, & 10 ARE ALSO RELATED TO THIS DIAGNOSIS PER PI.' reason for change: New Information	Heather Douds (b) (4)	07 Jan 2021 20:01:43

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS PREVIOUSLY REPORTED ADVERSE EVENTS OF PERIPHERAL EDEMA AND SHORTNESS OF BREATH, ARE RETROSPECTIVELY, CONSISTENT WITH HYPERTHYROIDISM. WE ARE TRYING TO CONTACT THE ENDOCRINOLOGY DIVISION AT THE VA FOR FURTHER CLARIFICATION. SEE NARRATIVES FOR SAE 2 & 3. AEs number 8, 9, & 10 are also related to this diagnosis per PI.' reason for change: New Information	Heather Douds (b) (4) (b) (4)	06 Jan 2021 15:48:31
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Jan 2021 22:04:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Jan 2021 22:04:33
DataPoint Un-verified.	Heather Douds (b) (4) (b) (4)	05 Jan 2021 22:04:33
User entered 'Subject has previously reported adverse events of peripheral edema and shortness of breath, are retrospectively, consistent with hyperthyroidism. We are trying to contact the endocrinology division at the VA for further clarification. See narratives for SAE 2 & 3.' reason for change: New Information	Heather Douds (b) (4) (b) (4)	05 Jan 2021 22:04:33
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Jan 2021 21:50:05
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:52:30
User entered empty.	Joan Siegner (b) (4) (b) (4)	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:13:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 21:50:05
User entered '0'	System	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:13:34

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	27 Oct 2020 17:20:45

US3552191

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Jan 2021 20:03:16

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User closed query 'Per DM CLR: Please specify the location and type of Itch and update with underlying etiology if known. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).		17 Dec 2020 08:53:32
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Generalized itching - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 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) (b) (4)	15 Dec 2020 20:32:53
Data point term sent to Coder	System	15 Dec 2020 20:31:22
Query 'Per DM CLR: Please specify the location and type of Itch and update with underlying etiology if known. 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).	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 20:30:34
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 20:30:29
User entered 'generalized ITCHING' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	15 Dec 2020 20:30:29
User opened query 'Per DM CLR: Please specify the location and type of Itch and update with underlying etiology if known. 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)	12 Dec 2020 06:49:14
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Itching - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 13:39:03

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Nov 2020 13:39:03
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 13:38:21
User entered 'itching'	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered '09 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User entered empty.	System	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	15 Mar 2021 17:16:56
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	15 Mar 2021 17:16:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:56:43
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.		18 Jan 2021 11:19:02
' (Site from DM).		
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.	Cassandra Zehenny (b) (4)	15 Jan 2021 21:49:26
' answered with 'ongoing per subject. will continue to follow up' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	14 Jan 2021 05:54:15
' (Site from DM).		
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	15 Mar 2021 17:16:56
	(b) (4)	
User entered '1 Feb 2021' reason for change: Data Entry Error	Heather Douds (b) (4)	15 Mar 2021 17:16:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User entered empty.	System	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered '0'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered '0'	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:56:43
User entered '0'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:56:43
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered '0'	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered '0'	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:56:43
User entered '0'	(b) (4), (b) (6)	02 Feb 2021 16:56:43
	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'Related (RELATED)' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	28 Dec 2020 17:06:55
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:56:43
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'None (NONE)'	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered '0'	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4) (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'l'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered '0'	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	15 Mar 2021 17:16:56
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Douds (b) (4)	15 Mar 2021 17:16:56
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4)	02 Feb 2021 16:56:43
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
	Stanley Dublin (b) (4)	19 Nov 2020 13:37:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:56:43
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User entered '0'	System	19 Nov 2020 13:37:33

US3552191

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54
User entered '0'	System	19 Nov 2020 13:37:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:13:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 04:27:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:13:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:15:03
User closed query 'Per ETRTR: According to SAE "Shortness of Breath" and SAE "Bilateral Ankle Edema", medication was dosed for both SAEs. Please confirm details on medication dosed, thanks' (Site from CRA).		15 Oct 2020 02:03:24
Query 'Per ETRTR: According to SAE "Shortness of Breath" and SAE "Bilateral Ankle Edema", medication was dosed for both SAEs. Please confirm details on medication dosed, thanks' answered with 'Noted, thank you.' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:26:25
User opened query 'Per ETRTR: According to SAE "Shortness of Breath" and SAE "Bilateral Ankle Edema", medication was dosed for both SAEs. Please confirm details on medication dosed, thanks' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 22:46:16
Query 'Per ETRTR: According to SAE "Bilateral Ankle Edema", medication was dosed for SAE. Please confirm details on medication dosed, thanks.' canceled (Site from CRA).		13 Oct 2020 22:45:35
User opened query 'Per ETRTR: According to SAE "Bilateral Ankle Edema", medication was dosed for SAE. Please confirm details on medication dosed, thanks.' (Site from CRA).		13 Oct 2020 22:39:20
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:07:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User closed query 'Please add EKG, chest Xray CT to the Concomitant procedures eCRF .' (Site from CRA).		24 Oct 2020 23:23:20
Query 'Please add EKG, chest Xray CT to the Concomitant procedures eCRF .' answered with 'see narrative' (Site from CRA).	Heather Douds (b) (4)	15 Oct 2020 15:33:22
User opened query 'Please add EKG, chest Xray CT to the Concomitant procedures eCRF .' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 14:12:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 19:25:36
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 19:25:36
Data point term sent to Coder	System	27 Aug 2020 15:13:04
User entered 'METFORMIN' reason for change:	Stanley Doublin (b) (4)	27 Aug 2020 15:12:59
Data Entry Error	(b) (4)	
User entered 'methormin'	Stanley Doublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'type 2 diabetes mellitus'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:33
Signature has been broken.	(b) (4) Cassandra Zehenny (b) (4)	09 Apr 2021 18:11:12
User signature succeeded.	(b) (4) sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '500'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'twice daily (BID)'	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un Jun 2018'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:12:40
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:12:40

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:38
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:17 28 Oct 2020 17:34:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:42:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 10:42:49
Data point term sent to Coder User entered 'HCTZ / triamterene'	System Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:14:05 27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'meniere's disease'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '25 / 37.5'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2015'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:14:02
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:14:02

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:19 28 Oct 2020 17:34:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:25:48
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 19:25:48
Data point term sent to Coder User entered 'atorvastatin'	System Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:16:07 27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'hypercholesterolemia'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '40'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2010'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:15:31
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:15:31

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:21 28 Oct 2020 17:34:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:26:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:26:19
Data point term sent to Coder	System	27 Aug 2020 15:18:17
User entered 'VENLAFAXINE' reason for change: Data Entry Error	Stanley Doublin (b) (4)	27 Aug 2020 15:17:26
Data point term sent to Coder	System	27 Aug 2020 15:17:15
User entered 'vanlafazine'	Stanley Doublin (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mild depression'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '75'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 1990'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:17:08
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:17:08

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
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: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:18 28 Oct 2020 17:34:15
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: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:31:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:31:15
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 14:55:39 05 Oct 2020 14:54:44
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: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:18
Data point term sent to Coder	System	27 Aug 2020 15:19:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'vitamin b12'	Stanley Doublin (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'REPLACEMENT for or preventative OF METFORMIN DEPLETION' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 14:54:44
User entered 'replacement for orpersentive of metformin depletion'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '1000'	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)' reason for change:	Cassandra Zehenny (b) (4)	05 Oct 2020 14:54:44
Data Entry Error	(b) (4)	
User entered 'once (ONCE)'	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un Jun 2018'	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User closed query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please verify and update either the frequency (e.g., Daily) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:23:07
Query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please verify and update either the frequency (e.g., Daily) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Correct' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	05 Oct 2020 14:54:51
User opened query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please verify and update either the frequency (e.g., Daily) or the start/end dates on the Con Med eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:19:19
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:18:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Oct 2020 14:54:44
User entered empty.	System	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Oct 2020 14:54:44
User entered empty.	System	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 14:54:44
User entered empty.	System	27 Aug 2020 15:18:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
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.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:24 28 Oct 2020 17:34:15
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)	27 Aug 2020 19:26:18
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 19:26:18
Data point term sent to Coder User entered 'gabapentin'	System Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:20:19 27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'osteoarthritis'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '300'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'as needed (PRN)'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2016'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:19:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:19:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
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.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:23 28 Oct 2020 17:34:15
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)	27 Aug 2020 19:26:24
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 19:26:24
Data point term sent to Coder User entered 'vitamin d3'	System Stanley Doublin (b) (4) (b) (4)	27 Aug 2020 15:21:19 27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'vitamin d deficiency'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '50'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'ug (ug)'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2012'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Stanley Dublin (b) (4)	27 Aug 2020 15:20:46
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:20:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
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.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:42:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:26 28 Oct 2020 17:34:15
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)	02 Oct 2020 19:15:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:15:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:43:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:43:56

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
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)	28 Aug 2020 00:51:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 00:51:39
Data point term sent to Coder	System	27 Aug 2020 16:50:31
User entered 'centrum silver'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:58:38
DataPoint Un-verified.	Stanley Doublin (b) (4)	11 Nov 2020 16:41:13
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	11 Nov 2020 16:41:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'health promotion'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'l'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'tablet (TABLET)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2014'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:49:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:42:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:37
Data point term sent to Coder	System	28 Oct 2020 17:34:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Aug 2020 11:55:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Aug 2020 11:55:44
Data point term sent to Coder	System	27 Aug 2020 16:51:36
User entered 'magnesium citrate'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'constipation'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '250'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2019'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:50:46

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:24 28 Oct 2020 17:34:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:39:02
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 19:39:02
Data point term sent to Coder User entered 'cetirizine'	System Joan Siegner (b) (4)	27 Aug 2020 16:52:38 27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'seasonal allergies'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '10'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once daily (QD)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'un UNK 2017'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'Yes (Y)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Joan Siegner (b) (4)	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 16:51:39

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:53:53
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	09 Apr 2021 18:12:03 09 Apr 2021 18:11:53
User signature succeeded.	(b) (4) sharon frey (b) (4) (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:42:41
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:30 28 Oct 2020 17:34:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:01:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:01:37
Data point term sent to Coder	System	14 Oct 2020 15:39:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Lasix'	Cassandra Zehenny (b) (4) (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:02:33
DataPoint Verified.	(b) (4)	09 Apr 2021 18:50:37
User closed query 'Please consider updating to Graves disease, as SAE term has been updated to Graves. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:50:25
Query 'Please consider updating to Graves disease, as SAE term has been updated to Graves. Thank you! ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	09 Apr 2021 18:12:03
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Cassandra Zehenny (b) (4)	09 Apr 2021 18:11:53
User entered 'Graves' Disease' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	09 Apr 2021 18:11:53
User opened query 'Please consider updating to Graves disease, as SAE term has been updated to Graves. Thank you! ' (Site from CRA).	Cassandra Zehenny (b) (4)	09 Apr 2021 15:11:11
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
User entered 'Shortness of breath and bilateral lower leg edema'	(b) (4), (b) (6)	28 Oct 2020 17:34:15
	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '20'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered empty.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'once (ONCE)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered 'Intravenous (INTRAVENOUS)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:28:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 15:23:18
User entered '09 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 15:23:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '9 Oct 2020'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	09 Nov 2020 17:28:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:28:20
	Cassandra Zehenny (b) (4)	09 Nov 2020 15:23:18
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 15:23:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '9 Oct 2020'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Cassandra Zehenny (b) (4)	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User entered empty.	System	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User entered empty.	System	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:01
User entered empty.	System	14 Oct 2020 15:39:33

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 19:42:40
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	28 Oct 2020 17:34:28 28 Oct 2020 17:34:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:49:34
Data point term sent to Coder User entered 'coreg'	System Mikayla Frye (b) (4)	27 Oct 2020 16:48:55 27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 17:34:15
	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'tachycardia'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered '6.25'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered 'mg (mg)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered 'twice daily (BID)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4)	
	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	28 Oct 2020 17:34:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	(b) (4)	
	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '26 Oct 2020'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered '0'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:58:53
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). Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated, thank you' (Site from DM).	(b) (4)	18 Jan 2021 11:56:45
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	14 Jan 2021 17:03:51
User entered 'No (N)' reason for change: New Information	(b) (4)	14 Jan 2021 17:03:44
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).	Cassandra Zehenny (b) (4)	14 Jan 2021 17:03:44
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 05:53:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 17:34:15
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint inactivated with code reason code Data not required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:58:56
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	14 Jan 2021 17:03:44
User entered '30 Oct 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	14 Jan 2021 17:03:44
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered empty.	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:34:15
User entered 'No (N)'	Mikayla Frye (b) (4)	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	Heather Douds (b) (4)	15 Oct 2020 15:27:47

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User entered '2'	System	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User entered 'I'	System	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:04
User entered '804 (804)'	System	27 Oct 2020 16:48:36
DataPoint activated with code reason code Data required.	Mikayla Frye (b) (4)	27 Oct 2020 16:47:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Heather Douds (b) (4)	15 Oct 2020 15:27:47
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. ' (Site from CRA).	(b) (4)	
Query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. ' answered with 'please see con med #13' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:10:48
User opened query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. ' (Site from CRA).	Heather Douds (b) (4)	13 Nov 2020 20:07:25
Query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. Also indication for Methimazole is hyperthyroidism . Since this condition is not listed in subject's medical history, please consider capturing this as an AE. Thank you! ' canceled (Site from CRA).	(b) (4)	
User opened query 'Please add Methimazole 30mg daily PO start date 26Oct- ongoing, per source. Also indication for Methimazole is hyperthyroidism . Since this condition is not listed in subject's medical history, please consider capturing this as an AE. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:53:09
DataPoint Verified.		13 Nov 2020 18:52:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\202003.		13 Nov 2020 18:51:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	05 Nov 2020 21:18:28
Data point term sent to Coder User entered 'Atenolol'	Coder Import (b) (4)	29 Oct 2020 19:47:56
	Coder Import (b) (4)	29 Oct 2020 19:47:56
	System	28 Oct 2020 18:26:55
	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:30
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:18:32
User entered 'Tachycardia'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:33
User entered '25'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:18:35
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:36
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:38
User entered 'twice daily (BID)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:39
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:41
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:43
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:44
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	30 Oct 2020 17:02:28
User entered '30 Oct 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	30 Oct 2020 17:02:28
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Oct 2020 18:26:53
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:46
User entered '0'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:53:59
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:53:59
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:29:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 13:29:42
DataPoint Verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:29:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:49
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:00:32
DataPoint Un-verified.	(b) (4), (b) (6)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 22:46:12
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	10 Dec 2020 22:46:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:54:01
DataPoint Un-verified.	Stanley Doublin (b) (4)	19 Nov 2020 13:29:42
	(b) (4)	
User entered '09 Nov 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Nov 2020 13:29:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:50
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:18:52
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 18:26:53

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User entered '2'	System	28 Oct 2020 18:26:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User entered '1'	System	28 Oct 2020 18:26:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:14
User entered '804 (804)'	System	28 Oct 2020 18:26:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 15:51:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 15:51:10
Data point term sent to Coder	System	30 Nov 2020 15:49:38
Coding entries removed.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:05
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:32:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:32:01
Data point term sent to Coder	System	19 Nov 2020 13:31:13
User entered 'methimazole'	Stanley Dublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:11
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:54:11
	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:01:06
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:53
User entered 'Graves' Disease' reason for change: New Information	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:12
User entered 'hyperthyroidism'	Stanley Dublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:14
User entered '30'	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:15
User entered 'mg (mg)'	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:17
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:20
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:22
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:23
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:24
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 17. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	15 Dec 2020 10:38:12
"		
' (Site from DM).		
Query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 17. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:45:40
"	(b) (4)	
' answered with 'updated' (Site from DM).		
User opened query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 17. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	10 Dec 2020 07:33:03
"		
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:26
User entered '26 Oct 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:30:54
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:27
User entered '0'	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:28
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 13:30:54
	Stanley Doublin (b) (4)	
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:01:10
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:45:36
User entered '08 Nov 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	10 Dec 2020 22:45:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:30
User entered '09 Nov 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:31
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User entered '1'	System	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User entered '1'	System	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:36
User entered '804 (804)'	System	19 Nov 2020 13:30:54

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:32:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:32:57
Data point term sent to Coder	System	19 Nov 2020 13:32:14
User entered 'atenolol'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:40
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:41
User entered 'tachycardia'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:43
User entered '50'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:44
User entered 'mg (mg)'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:54:57
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:54:58
User entered 'twice daily (BID)'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:55:00
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:01
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:03
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 14. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	14 Dec 2020 11:11:17
"		
' (Site from DM).		
Query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 14. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	Cassandra Zehenny (b) (4)	10 Dec 2020 22:46:28
"		
' answered with 'updated' (Site from DM).		
User opened query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 14. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	10 Dec 2020 07:33:16
"		
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:04
User entered '09 Nov 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:31:50
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:06
User entered '0'	Stanley Dublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:01:24
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 17:01:24
DataPoint Un-verified.	Stanley Doublin (b) (4)	08 Dec 2020 19:13:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 19:13:58
DataPoint Verified.	Stanley Doublin (b) (4)	08 Dec 2020 19:13:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:07
User entered 'Yes (Y)'	(b) (4)	24 Nov 2020 19:55:07
	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50
	(b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:01:27
DataPoint Un-verified.	Stanley Doublin (b) (4)	08 Dec 2020 19:13:58
User entered '02 Dec 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	08 Dec 2020 19:13:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:08
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:10
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User entered '2'	System	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User entered 'I'	System	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:40
User entered '804 (804)'	System	19 Nov 2020 13:31:50

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 15:50:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 15:50:54
Data point term sent to Coder	System	30 Nov 2020 15:49:38
Coding entries removed.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:41
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: SULFUR-CONTAINING IMIDAZOLE DERIVATIVES, PRODUCT: THIAMAZOLE, PRODUCTSYNONYM: METHIMAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:41:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:41:01
Data point term sent to Coder	System	19 Nov 2020 13:40:22
User entered 'methimazole'	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:55:18
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:01:43
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:41
User entered 'Graves' Disease' reason for change: New Information	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:41
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:20
User entered 'hyerthyroidism'	Stanley Dublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:21
User entered '40'	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:23
User entered 'mg (mg)'	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:24
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:31
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:32
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:33
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:35
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:36
User entered '09 Nov 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:38
User entered '0'	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:01:57
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:28:17
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	30 Nov 2020 15:28:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:39
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:01:59
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:28:17
User entered '18 Nov 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	30 Nov 2020 15:28:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:41
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:55:42
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:55:42
	Stanley Doublin (b) (4)	19 Nov 2020 13:39:23
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User entered 'I'	System	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User entered '1'	System	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:43
User entered '804 (804)'	System	19 Nov 2020 13:39:23

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 15:49:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 15:49:52
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:35 30 Nov 2020 15:48:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:41:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:41:00
Data point term sent to Coder User entered 'benadryl'	System Stanley Doublin (b) (4)	19 Nov 2020 13:40:23 19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:55:52
User entered 'No (N)'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:02:12
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:30
	(b) (4)	
User entered 'generalized ITCHING' reason for change: New Information	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:55:53
User entered 'itching'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:55:55
User entered '25'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:56
User entered 'mg (mg)'	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:55:58
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:02
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:03
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:04
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:06
User entered '09 Nov 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:07
User entered '0'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:08
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:09
User entered empty.	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:11
User entered 'No (N)'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 13:40:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:20
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)	19 Nov 2020 13:41:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:41:58
Data point term sent to Coder	System	19 Nov 2020 13:41:24
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:21
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:56:22
User entered 'influenza prophylaxis'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User closed query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs. ' (Site from DM).	(b) (4)	28 Jan 2021 06:47:37
Query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs. ' answered with 'Data is not unknown, data is correct as entered' (Site from DM).	Heather Douds (b) (4)	25 Jan 2021 18:19:28
User opened query 'Per CDM Re-Query: If Dose per administration is Unknown, please record as UNK per CCGs. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:31:58
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 10:31:58
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 23:01:25
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 08:37:16
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:24
User entered 'I'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:25
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:56:27
User entered 'injection'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:56:28
User entered 'once (ONCE)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 19:56:29
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:32
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:34
User entered '30 Oct 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:35
User entered '0'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:37
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:38
User entered '30 Oct 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:39
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User entered empty.	System	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User entered empty.	System	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:47
User entered empty.	System	19 Nov 2020 13:40:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:23
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).	(b) (4), (b) (6)	07 Jan 2021 10:30:57
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 'was not taken before screening' (Site from DM).	Cassandra Zehenny (b) (4)	05 Jan 2021 16:51:36
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)	04 Jan 2021 09:52:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Dec 2020 09:54:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Dec 2020 09:54:09
Data point term sent to Coder	System	30 Nov 2020 15:48:36
Data point term sent to Coder	System	30 Nov 2020 15:32:18
User entered 'Prednisone'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:23
User entered 'No (N)'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:23
User entered 'Graves' Disease' reason for change:	Cassandra Zehenny (b) (4)	30 Nov 2020 15:48:11
New Information	(b) (4)	
User entered 'Hyperthyroidism'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered '30'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered empty.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered empty.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered empty.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered '19 Nov 2020'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered '0'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 22:09:43
User closed query 'Per source end date 18Dec2020, please reconcile' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 22:09:40
Query 'Per source end date 18Dec2020, please reconcile' answered with 'updated, thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	02 Feb 2021 21:54:51
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:54:44
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	02 Feb 2021 21:54:44
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User opened query 'Per source end date 18Dec2020, please reconcile' (Site from CRA).	(b) (4)	02 Feb 2021 17:03:56
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 22:09:45
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 22:09:45
	Cassandra Zehenny (b) (4)	02 Feb 2021 21:54:44
User entered '18 Dec 2020' reason for change: New Information	(b) (4)	02 Feb 2021 21:54:44
DataPoint Verified.	Cassandra Zehenny (b) (4)	02 Feb 2021 17:06:23
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered 'No (N)'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User entered 'I'	System	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User entered '1'	System	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:03:51
User entered '804 (804)'	System	30 Nov 2020 15:32:00

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: OTHER ANTITHYROID PREPARATIONS, PRODUCT: PROPRANOLOL, PRODUCTSYNONYM: PROPANOLOL [PROPRANOLOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Feb 2021 11:51:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Feb 2021 11:51:45
Data point term sent to Coder Coding entries removed.	System Cassandra Zehenny (b) (4)	02 Feb 2021 21:56:59 02 Feb 2021 21:56:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: OTHER ANTITHYROID PREPARATIONS, PRODUCT: PROPRANOLOL, PRODUCTSYNONYM: PROPANOLOL [PROPRANOLOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 13:16:45
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 13:16:45
Data point term sent to Coder	System	08 Dec 2020 19:15:30
User entered 'propanolol'	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:34
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 17:06:34
	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
DataPoint Verified.		09 Apr 2021 15:46:17
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	02 Feb 2021 21:56:18
User entered 'Graves Disease' reason for change:	(b) (4)	
New Information	Cassandra Zehenny (b) (4)	02 Feb 2021 21:56:18
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered 'hyperthyroidism'	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered '10'	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered 'mg (mg)'	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered empty.	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered 'three times daily (TID)'	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:34
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered empty.	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:34
User entered '02 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered '03 Dec 2020'	Mikayla Frye (b) (4)	22 Jan 2021 14:42:07
	(b) (4)	
	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered '0'	Stanley Dublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:34
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	22 Jan 2021 14:41:17
	(b) (4)	
	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered '17 Jan 2021' reason for change: New Information	Mikayla Frye (b) (4)	22 Jan 2021 14:42:07
User entered '19 Jan 2021' reason for change: New Information	Mikayla Frye (b) (4)	22 Jan 2021 14:41:17
User entered empty.	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:34
User entered 'No (N)'	Stanley Doublin (b) (4)	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User entered '3'	System	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User entered '1'	System	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:35
User entered '804 (804)'	System	08 Dec 2020 19:15:03

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User closed query 'Please check spelling - Propanolol ' (Site from CRA).	(b) (4)	09 Apr 2021 18:52:16
Query 'Please check spelling - Propanolol ' answered with 'propranolol is correct spelling, updated source doc. thank you!' (Site from CRA).	Cassandra Zehenny (b) (4)	09 Apr 2021 18:13:11
User opened query 'Please check spelling - Propanolol ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:24:46
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: OTHER ANTITHYROID PREPARATIONS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 16:19:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 16:19:44
Data point term sent to Coder	System	23 Dec 2020 16:18:37
User entered 'Propranolol'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered 'No (N)'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:36
User entered 'Grave's disease'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered '10'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered 'mg (mg)'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered empty.	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:36
User entered 'twice daily (BID)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered empty.	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered empty.	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered '19 Dec 2020'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered '0'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:36
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	22 Jan 2021 14:42:34
	(b) (4)	
	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered '19 Jan 2021' reason for change: New Information	Mikayla Frye (b) (4)	22 Jan 2021 14:42:34
User entered empty.	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:36
User entered 'No (N)'	Mikayla Frye (b) (4)	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User entered '2'	System	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User entered '1'	System	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:29
User entered '804 (804)'	System	23 Dec 2020 16:17:55

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
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).	(b) (4), (b) (6)	11 Feb 2021 12:27:06
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 "'prior to screening" does not meet exclusion criteria' (Site from DM).	Cassandra Zehenny (b) (4)	09 Feb 2021 16:20:24
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)	09 Feb 2021 11:59:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 17:22:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 17:22:54
Data point term sent to Coder	System	23 Dec 2020 16:18:38

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'prednisone'	Mikayla Frye (b) (4) (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered 'No (N)'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:39
User entered 'grave's disease'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered '25'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered 'mg (mg)'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:39
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered 'once daily (QD)'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered empty.	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered empty.	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:39
User entered '19 Dec 2020'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:39
User entered '0'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:39
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	13 Jan 2021 20:15:24
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered '23 Dec 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	13 Jan 2021 20:15:24
User entered empty.	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered 'No (N)'	Mikayla Frye (b) (4)	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User entered 'I'	System	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User entered 'I'	System	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:26
User entered '804 (804)'	System	23 Dec 2020 16:18:36

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
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)	15 Jan 2021 09:56:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 09:56:49
Data point term sent to Coder	System	13 Jan 2021 20:17:59
User entered 'PREDNISONE'	Stanley Doublin (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'graves disease'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '10'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'mg (mg)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'once daily (QD)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '07 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	13 Jan 2021 20:23:25
User entered '01 Jan 2021'	(b) (4)	
	Stanley Dublin (b) (4)	13 Jan 2021 20:17:48
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:23:25
User entered '07 Jan 2021'	(b) (4)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:17:48
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
DataPoint Verified.		09 Apr 2021 15:33:01
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
User entered 'I'	System	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
User entered '1'	System	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:45
User entered '804 (804)'	System	13 Jan 2021 20:17:48

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
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)	15 Jan 2021 09:56:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 09:56:49
Data point term sent to Coder	System	13 Jan 2021 20:23:01
User entered 'PREDNISONE'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:43
User entered 'graves disease'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered '15'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:43
User entered 'mg (mg)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered '31 Dec 2020'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered '0'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 20:22:23
User entered '06 Jan 2021' reason for change: Data Entry Error	Stanley Dublin (b) (4)	13 Jan 2021 20:22:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 20:22:17
User entered '06 Jan ' (non-conformant).	Stanley Dublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:43
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User entered 'I'	System	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User entered '1'	System	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:52
User entered '804 (804)'	System	13 Jan 2021 20:22:17

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
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)	15 Jan 2021 09:56:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 09:56:50
Data point term sent to Coder	System	13 Jan 2021 20:25:03
User entered 'PREDNISONE'	Stanley Dublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered 'graves disease'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered '20'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:46
User entered 'mg (mg)'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered '24 Dec 2020'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered '0'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered '30 Dec 2020'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:46
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User entered 'I'	System	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User entered '1'	System	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:55
User entered '804 (804)'	System	13 Jan 2021 20:24:09

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
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)	15 Jan 2021 09:56:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 09:56:50
Data point term sent to Coder	System	13 Jan 2021 20:25:03
User entered 'PREDNISONE'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered 'graves disease'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered '5'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:51
User entered 'mg (mg)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:51
User entered empty.	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered empty.	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	20 Jan 2021 15:16:51
User entered '14 Jan 2021' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	20 Jan 2021 15:16:51
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	20 Jan 2021 15:16:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	20 Jan 2021 15:16:41
User entered empty; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	20 Jan 2021 15:16:41
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Jan 2021 20:24:42
User entered '14 Jan 2021'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered '0'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:51
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	22 Jan 2021 14:43:33
	(b) (4)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 17:06:51
User entered '19 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered empty.	Mikayla Frye (b) (4)	22 Jan 2021 14:43:33
	(b) (4)	
	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42
	(b) (4)	

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:51
User entered 'No (N)'	Stanley Doublin (b) (4)	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User entered 'I'	System	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User entered '1'	System	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:04:58
User entered '804 (804)'	System	13 Jan 2021 20:24:42

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Feb 2021 17:20:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 17:20:01
Data point term sent to Coder	System	22 Feb 2021 17:19:07
User entered 'levothyroxine'	Stanley Doublin (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'graves disease'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '100'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'ug (ug)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'once daily (QD)'	(b) (4) Stanley Dublin (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Oral (ORAL)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:01:22
User signature succeeded.	sharon frey (b) (4)	26 Feb 2021 03:21:19
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:13:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 17:19:04

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:13:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:26
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:57:04
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:37:56
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Cassandra Zehenny (b) (4)	30 Nov 2020 15:37:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:26:09
User entered 'No (N)'	Cassandra Zehenny (b) (4)	09 Nov 2020 15:31:36
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:57:10
User entered '24 Nov 2020'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:38:23
	(b) (4)	

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:57:10
User entered 'Radioactive Iodine uptake Scan'	Cassandra Zehenny (b) (4)	30 Nov 2020 15:38:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:10
User entered 'Diagnostic (DIAGNOSTIC)'	Cassandra Zehenny (b) (4) (b) (4)	30 Nov 2020 15:38:23

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:13:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:57:10
User entered empty.	Cassandra Zehenny (b) (4)	30 Nov 2020 15:38:23
	(b) (4)	

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:57:12
User entered '01 Dec 2020'	Stanley Doublin (b) (4)	08 Dec 2020 19:12:51

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	02 Feb 2021 16:57:12
User entered 'thyroid ablation'	(b) (4), (b) (6)	02 Feb 2021 16:57:12
	Stanley Doublin (b) (4)	08 Dec 2020 19:12:51
	(b) (4)	

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:57:12
User entered 'Adverse Event (AE)'	Stanley Dublin (b) (4)	08 Dec 2020 19:12:51

US3552191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:13:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:57:12
User entered empty.	Stanley Dublin (b) (4)	08 Dec 2020 19:12:51

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.		13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:12:56
User entered '12/Oct/2020 08:43'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:12:57
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'I'		12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:13:19
User entered '13/Oct/2020 13:30'	System	13 Oct 2020 13:30:31

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 15:24:05
User entered 'I'		13 Oct 2020 13:30:31

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:13:13
User entered '13/Oct/2020 15:24'	System	13 Oct 2020 15:24:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 15:29:45
User entered 'I'		13 Oct 2020 15:24:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:13:40
User entered '15/Oct/2020 08:28'	System	15 Oct 2020 12:28:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:13:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		15 Oct 2020 12:29:01
User entered 'l'		15 Oct 2020 12:28:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

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Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.		13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:13:48
User entered '15/Oct/2020 08:44'	System	15 Oct 2020 12:44:51

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:13:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:20:15
User entered 'l'		15 Oct 2020 12:44:51

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.		13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:13:58
User entered '15/Oct/2020 20:20'	System	16 Oct 2020 00:20:24

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:13:59
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:23:32
User entered 'l'		16 Oct 2020 00:20:24

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:14:05
User entered '22/Oct/2020 17:23'	System	22 Oct 2020 17:23:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:14:07
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 17:24:10
User entered 'l'		22 Oct 2020 17:23:57

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:14:18
User entered '26/Oct/2020 13:05'	System	26 Oct 2020 13:05:43

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	05 Nov 2020 21:14:20
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:07:28
User entered 'l'		26 Oct 2020 13:05:43

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:14:34
User entered '29/Oct/2020 11:07'	System	29 Oct 2020 15:07:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
Reviewed for Safety.	(b) (4)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:14:39
User entered 'l'		29 Oct 2020 15:07:38

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:33:37
User entered '10/Nov/2020 19:08'	System	10 Nov 2020 19:08:45

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
Reviewed for Safety.	(b) (4)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:35
User entered 'l'		10 Nov 2020 19:08:45

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
User entered '1100 S. Grand Blvd'	(b) (4), (b) (6)	09 Nov 2020 17:19:34
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:36:49
User entered '12/Nov/2020 14:28'	System	12 Nov 2020 14:28:04

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:50
User entered 'l'		12 Nov 2020 14:28:04

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

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Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:00:31
User entered '20/Nov/2020 21:48'	System	20 Nov 2020 21:48:13

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	24 Nov 2020 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 02:55:32
User entered 'l'		20 Nov 2020 21:48:13

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.		13 Nov 2020 18:34:48
DataPoint Verified.		13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	System	10 Nov 2020 19:08:45
	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:00:36
User entered '23/Nov/2020 21:55'	System	24 Nov 2020 02:55:43

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
Reviewed for Safety.	(b) (4)	25 Nov 2020 12:37:31
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:00:37
User entered 'l'		24 Nov 2020 02:55:43

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:09
User entered '25/Nov/2020 12:37'	System	25 Nov 2020 12:37:49

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:11
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 20:55:54
User entered 'l'		25 Nov 2020 12:37:49

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'USA-US089-2020-MRNA-1273-P301000009'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Death

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:24
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'Yes (Y)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:28
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 12:43:19
User entered 'No (N)'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'sharon'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:32
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'frey'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:48
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:34:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:04
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:34
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 21:47:51
DataPoint Verified.		13 Nov 2020 18:36:46
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:06
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:36
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		12 Oct 2020 12:43:19
User entered 'MO'	System	12 Oct 2020 12:43:02

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
Reviewed for Safety.	(b) (4)	20 Nov 2020 21:47:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 18:36:47
Un-reviewed for Safety.	System	12 Nov 2020 14:28:04
DataPoint Un-verified.	System	12 Nov 2020 14:28:04
User entered empty.	System	12 Nov 2020 14:28:04
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:27:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:33:08
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:54
Un-reviewed for Safety.	(b) (4)	10 Nov 2020 19:08:45
DataPoint Un-verified.	System	10 Nov 2020 19:08:45
User entered empty.	System	10 Nov 2020 19:08:45
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:07:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:39
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:38:53
	(b) (4)	

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	30 Oct 2020 15:48:35
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:44:38
Un-reviewed for Safety.		15 Oct 2020 12:44:36
Reviewed for Safety.		13 Oct 2020 13:30:21
User entered 'US'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '15'	System	04 Jan 2021 20:55:48
User entered '14'	System	25 Nov 2020 12:37:49
User entered '13'	System	24 Nov 2020 02:55:43
User entered '12'	System	20 Nov 2020 21:48:13
User entered '11'	System	12 Nov 2020 14:28:04
User entered '10'	System	10 Nov 2020 19:08:45
User entered '9'	System	29 Oct 2020 15:07:38
User entered '8'	System	26 Oct 2020 13:05:43
User entered '7'	System	22 Oct 2020 17:23:57
User entered '6'	System	16 Oct 2020 00:20:24
User entered '5'	System	15 Oct 2020 12:44:51
User entered '4'	System	15 Oct 2020 12:28:57
User entered '3'	System	13 Oct 2020 15:24:38
User entered '2'	System	13 Oct 2020 13:30:31
User entered '1'	System	12 Oct 2020 12:43:25

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (15)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:15
User entered '04/Jan/2021 15:55'	System	04 Jan 2021 20:55:48

US3552191

Folder: SAE USA-US089-2020-MRNA-1273-P301000009

Form: Safety Report Form (15)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 20:55:54
User entered 'l'		04 Jan 2021 20:55:48

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'USA-US089-2021-MRNA-1273-P301000001'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	07 Jan 2021 20:01:43
User entered 'Yes (Y)'	System	07 Jan 2021 20:01:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'sharon'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'frey'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '1100 S. Grand'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'Saint Louis'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'MO'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '63104'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		06 Jan 2021 16:07:12
User entered 'US'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Mar 2021 16:45:02
User entered '5'	System	16 Mar 2021 16:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '4'	System	19 Jan 2021 15:29:15
User entered '3'	System	07 Jan 2021 21:15:35
User entered '2'	System	06 Jan 2021 16:07:27
User entered '1'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'USA-US089-2021-MRNA-1273-P301000001'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	07 Jan 2021 20:01:43
User entered 'Yes (Y)'	System	07 Jan 2021 20:01:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'sharon'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'frey'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '1100 S. Grand'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'Saint Louis'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'MO'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '63104'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'US'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Mar 2021 16:45:02
User entered '5'	System	16 Mar 2021 16:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '4'	System	19 Jan 2021 15:29:15
User entered '3'	System	07 Jan 2021 21:15:35
User entered '2'	System	06 Jan 2021 16:07:27
User entered '1'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
User entered '06/Jan/2021 09:47'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'l'		06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'USA-US089-2021-MRNA-1273-P301000001'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	07 Jan 2021 20:01:43
User entered 'Yes (Y)'	System	07 Jan 2021 20:01:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'sharon'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'frey'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '1100 S. Grand'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'Saint Louis'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'MO'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '63104'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'US'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Mar 2021 16:45:02
User entered '5'	System	16 Mar 2021 16:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '4'	System	19 Jan 2021 15:29:15
User entered '3'	System	07 Jan 2021 21:15:35
User entered '2'	System	06 Jan 2021 16:07:27
User entered '1'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
User entered '06/Jan/2021 11:07'	System	06 Jan 2021 16:07:27

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
User entered 'l'		06 Jan 2021 16:07:27

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'USA-US089-2021-MRNA-1273-P301000001'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	07 Jan 2021 20:01:43
User entered 'Yes (Y)'	System	07 Jan 2021 20:01:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'sharon'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'frey'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '1100 S. Grand'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'Saint Louis'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'MO'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '63104'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'US'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Mar 2021 16:45:02
User entered '5'	System	16 Mar 2021 16:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '4'	System	19 Jan 2021 15:29:15
User entered '3'	System	07 Jan 2021 21:15:35
User entered '2'	System	06 Jan 2021 16:07:27
User entered '1'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
User entered '07/Jan/2021 21:15'	System	07 Jan 2021 21:15:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 15:29:02
User entered 'l'		07 Jan 2021 21:15:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'USA-US089-2021-MRNA-1273-P301000001'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	07 Jan 2021 20:01:43
User entered 'Yes (Y)'	System	07 Jan 2021 20:01:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'sharon'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'frey'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '1100 S. Grand'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'Saint Louis'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'MO'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '63104'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'US'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Mar 2021 16:45:02
User entered '5'	System	16 Mar 2021 16:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '4'	System	19 Jan 2021 15:29:15
User entered '3'	System	07 Jan 2021 21:15:35
User entered '2'	System	06 Jan 2021 16:07:27
User entered '1'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
User entered '19/Jan/2021 10:29'	System	19 Jan 2021 15:29:15

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:13:34

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 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
User entered 'l'	(b) (4), (b) (6)	19 Jan 2021 15:29:15

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'USA-US089-2021-MRNA-1273-P301000001'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	07 Jan 2021 20:01:43
User entered 'Yes (Y)'	System	07 Jan 2021 20:01:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'sharon'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'frey'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '1100 S. Grand'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'Saint Louis'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'MO'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '63104'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		06 Jan 2021 16:07:12
User entered 'US'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Mar 2021 16:45:02
User entered '5'	System	16 Mar 2021 16:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '4'	System	19 Jan 2021 15:29:15
User entered '3'	System	07 Jan 2021 21:15:35
User entered '2'	System	06 Jan 2021 16:07:27
User entered '1'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:02:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered '16/Mar/2021 12:25'	(b) (4) System	16 Mar 2021 16:25:34

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:13:34

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)	09 Apr 2021 16:02:39
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 16:25:34

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'USA-US089-2021-MRNA-1273-P301000001'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	07 Jan 2021 20:01:43
User entered 'Yes (Y)'	System	07 Jan 2021 20:01:43
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'Yes (Y)'	System	06 Jan 2021 14:46:38

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Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'No (N)'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		06 Jan 2021 14:47:24
User entered 'sharon'	System	06 Jan 2021 14:46:38

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Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		06 Jan 2021 14:47:24
User entered 'frey'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '1100 S. Grand'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.		07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'Saint Louis'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 14:47:24
User entered 'MO'	System	06 Jan 2021 14:46:38

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 21:15:24
Un-reviewed for Safety.	System	06 Jan 2021 16:07:27
User entered empty.	System	06 Jan 2021 16:07:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered '63104'	Heather Douds (b) (4)	06 Jan 2021 15:48:48
	(b) (4)	

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Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:25:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 16:07:12
User entered 'US'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:13:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Mar 2021 16:45:02
User entered '5'	System	16 Mar 2021 16:25:34
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 18:11:12
	(b) (4)	
User entered '4'	System	19 Jan 2021 15:29:15
User entered '3'	System	07 Jan 2021 21:15:35
User entered '2'	System	06 Jan 2021 16:07:27
User entered '1'	System	06 Jan 2021 14:47:35

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:13:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 16:02:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered '16/Mar/2021 12:45'	(b) (4) System	16 Mar 2021 16:45:02

US3552191

Folder: SAE USA-US089-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:13:34

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)	09 Apr 2021 16:02:38
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:29:15
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 16:45:02