

US3182192 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:35:05

All time stamps listed in this document are displayed in GMT

US3182192

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:35:19

Generated On: 09 Jun 2021 15:35:05

Participant ID

US3182192

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

US3182192

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

US3182192

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
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) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Date of Informed Consent (*dd MMM yyyy*) 6 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version
Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail
Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3182192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	TRIGEMINAL NEURALGIA
Start date (dd MMM yyyy)	UN OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	OSTEOARTHRITIS-RIGHT KNEE
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)	

US3182192

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	OSTEOPENIA
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 (8)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	DEVIATED SEPTUM
Start date (dd MMM yyyy)	17 JAN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182192

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	19 MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	GERD
Start date (dd MMM yyyy)	UN MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3182192

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

Condition	HEMORRHOIDS
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 (16)

Data signed: (b) (4) 26 Mar 2021 13:19:10

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:25 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:25
Height (<i>xxx.x</i>)	164.9 cm
Weight (<i>xxx.x</i>)	80.1 kg
BMI (<i>xxx.x</i>)	29.45718 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182192

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

06 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) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*) 06 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 1997

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:42:26

Generated On: 09 Jun 2021 15:35:05

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

OFFICE MANAGER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:42:26

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 AUG 2020

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

Folder OID VISIT1

US3182192

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 143112

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Height	ND - Not Done
Weight	ND - Not Done

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:25 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:25
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:38 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:38
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

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) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 10:03 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 10:03

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

US3182192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 06 AUG 2020

Collection time (*00:00-23:59*) 09:45 (24 HR)

Collection date and time (derived) 06 AUG 2020 09:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Collection date (<i>dd MMM yyyy</i>)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:30	06 AUG 2020 09:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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 98.2 °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 06 AUG 2020 10:34

PC Open Date & Time 06 AUG 2020 10:23

PC Close Date & Time 06 AUG 2020 12:53

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.5 °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 06 AUG 2020 17:52
PC Open Date & Time 06 AUG 2020 13:48
PC Close Date & Time 07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 AUG 2020 12:24
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 AUG 2020 18:01
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 18:18
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 AUG 2020 18:44
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 AUG 2020 17:31
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

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

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

PC Time Stamp	12 AUG 2020 18:12
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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

06 AUG 2020 10:37

PC Open Date & Time

06 AUG 2020 10:23

PC Close Date & Time

06 AUG 2020 12:53

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

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

06 AUG 2020 17:54

PC Open Date & Time

06 AUG 2020 13:48

PC Close Date & Time

07 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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	07 AUG 2020 12:25
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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	08 AUG 2020 18:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 AUG 2020 18:18

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	10 AUG 2020 18:45
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 AUG 2020 17:31

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 7

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	12 AUG 2020 18:13
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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

No

Yes

PC Time stamp	06 AUG 2020 10:37
PC Open Date & Time	06 AUG 2020 10:23
PC Close Date & Time	06 AUG 2020 12:53

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

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

No

Yes

PC Time stamp	06 AUG 2020 17:53
PC Open Date & Time	06 AUG 2020 13:48
PC Close Date & Time	07 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 12:26
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 18:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 18:18
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 18:45
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 03 SEP 2020

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

Folder OID VISIT2

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

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)	03 SEP 2020
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 09:19
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:40 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 10:40
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 10:05

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

US3182192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 03 SEP 2020

Collection time (*00:00-23:59*) 09:40 (24 HR)

Collection date and time (derived) 03 SEP 2020 09:40

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Collection date (<i>dd MMM yyyy</i>)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:30	03 SEP 2020 09:30
Nasopharyngeal Swab 2	No		

US3182192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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 97.5 °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 03 SEP 2020 10:38

PC Open Date & Time 03 SEP 2020 10:25

PC Close Date & Time 03 SEP 2020 12:55

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

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

PC Time Stamp 03 SEP 2020 19:09
PC Open Date & Time 03 SEP 2020 13:50
PC Close Date & Time 04 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 SEP 2020 21:15
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 SEP 2020 17:30
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 19:54
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 5

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 21:19
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 19:57
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 19:18
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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

03 SEP 2020 10:38

PC Open Date & Time

03 SEP 2020 10:25

PC Close Date & Time

03 SEP 2020 12:55

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

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

03 SEP 2020 19:10

PC Open Date & Time

03 SEP 2020 13:50

PC Close Date & Time

04 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

04 SEP 2020 21:16

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

05 SEP 2020 17:30

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 4

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	06 SEP 2020 19:54
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	07 SEP 2020 21:19
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 SEP 2020 19:57

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 SEP 2020 19:18

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

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

No

Yes

PC Time stamp	03 SEP 2020 10:39
PC Open Date & Time	03 SEP 2020 10:25
PC Close Date & Time	03 SEP 2020 12:55

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

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

No

Yes

PC Time stamp	03 SEP 2020 19:10
PC Open Date & Time	03 SEP 2020 13:50
PC Close Date & Time	04 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 21:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 17:30
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 19:55
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 21:20
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 19:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 19:18
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3182192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:20:32

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 01 OCT 2020

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

Folder OID VISIT3

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 01 OCT 2020

Time of assessment (00:00-23:59) 08:58 (24 HR)

Vital Signs Date and Time (derived) 01 OCT 2020 08:58

Temperature (xxx.x) 97.7 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 72 beats/min

Pulse units BPM

Respiratory Rate (xxx) 16 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 115 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 77 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3182192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

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.

US3182192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 01 OCT 2020

Collection time (*00:00-23:59*) 09:00 (24 HR)

Collection date and time (derived) 01 OCT 2020 09:00

US3182192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:15:15

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 08 OCT 2020 13:39:21

Patient Cloud Open Date & Time 06 OCT 2020 00:01

Patient Cloud Close Date & Time 10 OCT 2020 23:59

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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 15 OCT 2020 12:12:59

Patient Cloud Open Date & Time 13 OCT 2020 00:01

Patient Cloud Close Date & Time 17 OCT 2020 23:59

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 20 OCT 2020 09:43:18

Patient Cloud Open Date & Time 20 OCT 2020 00:01

Patient Cloud Close Date & Time 24 OCT 2020 23:59

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 03 NOV 2020 00:23:25

Patient Cloud Open Date & Time 03 NOV 2020 00:01

Patient Cloud Close Date & Time 07 NOV 2020 23:59

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 99

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 10 NOV 2020 15:46:05

Patient Cloud Open Date & Time 10 NOV 2020 00:01

Patient Cloud Close Date & Time 14 NOV 2020 23:59

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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	22 NOV 2020 18:03:00
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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 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	28 NOV 2020 08:49:44
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	05 DEC 2020 07:58:45
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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	12 DEC 2020 08:33:44
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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	21 DEC 2020 11:11:01
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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	26 DEC 2020 01:06:18
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 03:52:46
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 07:03:29
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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	18 JAN 2021 12:00:57
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 19:34:37
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 180

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

No

Yes

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

No

Yes

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

Date and time of submission 30 JAN 2021 16:49:19

Patient Cloud Open Date & Time 30 JAN 2021 00:01

Patient Cloud Close Date & Time 03 FEB 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 10:31:25
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 15 FEB 2021 15:29:30

Patient Cloud Open Date & Time 13 FEB 2021 00:01

Patient Cloud Close Date & Time 17 FEB 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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	23 FEB 2021 18:00:03
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 208

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

No
Yes

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

No
Yes

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

Date and time of submission	28 FEB 2021 21:17:19
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 04:14:46
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 MAR 2021 19:38:04
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 11:57:51
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 236

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

No

Yes

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

No

Yes

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

Date and time of submission

27 MAR 2021 00:02:48

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Have 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):

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

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

Date and time of submission 05 APR 2021 14:54:12

Patient Cloud Open Date & Time 03 APR 2021 00:01

Patient Cloud Close Date & Time 07 APR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	12 APR 2021 12:09:34
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	19 APR 2021 12:01:16
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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 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 APR 2021 12:01:58
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 320

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#) 30 JUN 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	31 JUL 2021 00:01
Patient Cloud Close Date & Time	04 AUG 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#) 18 AUG 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 411

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 439

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 446

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#) 27 OCT 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	27 NOV 2021 00:01
Patient Cloud Close Date & Time	01 DEC 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#) 22 DEC 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	02 MAR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 600

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 621

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 17 AUG 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

DAY 796

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

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

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

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

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

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

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

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

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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

[Patient Cloud Close Date & Time](#) 12 OCT 2022 23:59

US3182192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:35:05

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		28 FEB 2021 21:17:38

US3182192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 FEB 2021

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

Folder OID VISIT4

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:54:41

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:07 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:07
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3182192

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3182192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 FEB 2021

Collection time (*00:00-23:59*) 14:49 (24 HR)

Collection date and time (derived) 23 FEB 2021 14:49

US3182192

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 15:48:40

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:48:40

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

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 _____

US3182192

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3182192

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:35:05

Generate Next COVID-19 Assessment

Yes

No

US3182192

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3182192

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

Form: Unblinding

Data signed: (b) (4) 10 Apr 2021 21:24:36

Generated On: 09 Jun 2021 15:35:05

Date of updated informed consent (<i>dd MMM yyyy</i>)	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	28 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3182192

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Height	165.4 cm
Weight	78.3 kg
BMI (xxx.x)	28.62139

US3182192

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Height	165.4 cm
Weight	78.3 kg
BMI (xxx.x)	28.62139
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)	28 JAN 2021
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 14:50
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Height	165.4 cm
Weight	78.3 kg
BMI (xxx.x)	28.62139
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)	28 JAN 2021
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 15:50
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

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

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3182192

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

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 15:20 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 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

US3182192

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 28 JAN 2021

Collection time (*00:00-23:59*) 15:50 (24 HR)

Collection date and time (derived) 28 JAN 2021 15:50

US3182192

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 28 JAN 2021

Collection time (*00:00 - 23:59*) 14:50

Collection Date and Time (derived) 28 JAN 2021 14:50

US3182192

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

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 FEB 2021

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

Folder OID OLD29

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:07 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:07
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:17 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:17
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3182192

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3182192

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

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

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 09:47 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 09:47

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

What was the frequency of the study treatment dosing? ONCE

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

US3182192

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 17:03:24

Generated On: 09 Jun 2021 15:35:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3182192

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 17:03:24

Generated On: 09 Jun 2021 15:35:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3182192

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 03:43:36

Generated On: 09 Jun 2021 15:35:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 MAR 2021

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

Folder OID OLD57

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Mar 2021 03:43:36

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:05 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 09:05
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182192

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 03:43:36

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3182192

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 03:43:36

Generated On: 09 Jun 2021 15:35:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 MAR 2021

Collection time (*00:00-23:59*) 09:15 (24 HR)

Collection date and time (derived) 22 MAR 2021 09:15

US3182192

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:35:19

Generated On: 09 Jun 2021 15:35:05

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

AEID USA-US075-2020-MRNA-1273-P30
1000005

Adverse event SEVERE EPISTAXIS
SECONDARY TO NASAL
SURGICAL COMPLICATION

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) 22 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) 23 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 23 NOV 2020

Hospital Discharge Date (dd MMM yyyy) 26 NOV 2020

Admitted to ICU? Yes
No

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

ON NOVEMBER 11 SUBJECT WAS SEEN BY ENT TO HAVE SEPTOPLASTY PERFORMED TO REPAIR DEVIATED SEPTUM. SUBJECT HAD STENTS TAKEN OUT ON 11/18/20. SUBJECT REPORTS 2 SEVERE NOSE BLEEDS ON 11/20/20 AND 11/22/20. SUBJECT CALLED AMBULANCE ON 11/22/20 AROUND 10 P.M. AND WAS TAKEN TO ER. SUBJECT REPORTS SHE HAD SYNCOPAL EPISODE WHILE IN ER AND WAS TRANSFERRED TO METRO HOSPITAL DUE TO BLOOD LOSS. PATIENT REPORTS SHE REMAINS HOSPITALIZED AND WAS SEEN BY ENT SPECIALIST 11/25/20 TO ASSESS BLOOD IN AIRWAY. SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK AWAITING RESULTS. RECORDS WILL BE REQUESTED.

RECORDS RECEIVED. SUBJECT HAD SEPTOPLASTY PERFORMED ON 11/11/2020. ON 11/22/2020 SUBJECT WAS TAKEN TO THE ER BY AMBULANCE FOR NOSE BLEED. SUBJECT STATED THE NOSE BLED LASTED A FEW MINUTES

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

IN DURATION. AT ARRIVAL
THE SUBJECT WAS VERY
ANXIOUS AND COMPLAINED
OF CHEST TIGHTNESS AND
SUFFERED A BRIEF SYNCOPAL
EPISODE. THE SUBJECT
CONFIRMED THE CHEST
TIGHTNESS SUBSIDED AFTER
HER SYNCOPE SUBSIDED. IV
FLUIDS GIVEN. THE SUBJECT
HAD AN EKG (SINUS RHYTHM,
83BPM, LEFT AXIS DEVIATION,
NO ST ELEVATION,
NONSPECIFIC T WAVE
FLATTENING, NO EVIDENCE OF
ACUTE CRITERIA FOR CATH
LAB. LABS DRAWN, WITHIN
NORMAL LIMITS. TREATMENTS
GIVEN ADDED TO
APPROPRIATE LOGS

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

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

AEID	
Adverse event	SYNCOPE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 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 (2)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

AEID	
Adverse event	ANEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

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)

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

AEID _____

Adverse event _____ EPISTAXIS (SECONDARY TO
NASAL SURGERY)

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) _____ 20 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) _____ 20 NOV 2020

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

AE End Date and Time (derived) _____

Severity _____ Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death _____ False

Life threatening _____ False

Requires inpatient or prolongation of existing Hospitalization _____ False

Hospital Admission Date (dd MMM yyyy) _____

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes
No
Unknown

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

AEID

Adverse event

CHEST TIGHTNESS-UNKNOWN
ETIOLOGY

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)

22 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)

22 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

AEID USA-US075-2020-MRNA-1273-P30
1000005

Adverse event HYPOXIA SECONDARY TO
CHRONIC OBSTRUCTIVE
PULMONARY DISEASE AND
ASTHMA

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) 24 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) 25 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 23 NOV 2020

Hospital Discharge Date (dd MMM yyyy) 26 NOV 2020

Admitted to ICU? Yes

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 20:37:32

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No
Unknown

Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 20:37:32

Generated On: 09 Jun 2021 15:35:05

PER MEDICAL RECORDS
REVIEW, ON
11/24/2020-11/25/2020 SUBJECT
WAS HYPOXIC SECONDARY TO
HER HISTORY OF ASTHMA AND
COPD. THIS PROLONGED HER
HOSPITALIZATION AND THUS
IS A NEW SAE. CON MEDS
WERE GIVEN. SUBJECT WAS
STABLE AT DISCHARGE.

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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:35:44

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

Yes

No

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

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication OMEPRAZOLE

Prophylaxis Yes
No

Indication ACID REFLUX

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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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2009

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication CITALOPRAM

Prophylaxis Yes
No

Indication ANXIETY

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

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

	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 2000

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication HYPERTENSION

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 (3)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2000

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication METOPROLOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2003

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication AMLODIPINE

Prophylaxis Yes
No

Indication HYPERTENSION

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 (5)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2002

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 19:09:29

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Name of Medication TRELEGY

Prophylaxis Yes
No

Indication ASTHMA/CHRONIC
OBSTRUCTIVE PULMONARY
DISEASE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 19:09:29

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication ALBUTEROL

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 19:09:29

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- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2014

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication MULTIVITAMIN (UNKNOWN)

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication VITAMIN C

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

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 (9)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication VITAMIN B12

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNITS

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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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication VITAMIN K2

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication CENTRUM WOMEN

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2005

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

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 (13)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2009

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication GLUCOSAMINE

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2009

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication ZYRTEC

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2005

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication CLARITIN

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 2005

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication VOLTAREN

Prophylaxis Yes
No

Indication OSTEOARTHRITIS

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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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 15 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 2

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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*) 26 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 26 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication AFRIN NASAL SPRAY

Prophylaxis Yes
No

Indication NOSEBLEED (EPISTAXIS)

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify SPRAYS

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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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input checked="" type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 26 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 29 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication HYDROCORTISONE

Prophylaxis Yes
No

Indication HEMORRHOIDS

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 checked="" 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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication MIRALAX

Prophylaxis Yes
No

Indication STOOL
SOFTENER/CONSTIPATION
PROPHYLAXIS

Dose per administration 17

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

	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) 23 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication ZOLPIDEM

Prophylaxis Yes
No

Indication INSOMNIA

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 QPM
Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication OMEGA 3 ACID

Prophylaxis Yes
No

Indication HEALTH MAINTENANCE

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 23 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication SEPTOPLASTY PAIN

Dose per administration 650

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 23 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes
No

Indication SEPTOPLASTY PAIN

Dose per administration 5/325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

	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) 23 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 01 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication CLONAZEPAM

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 1.5

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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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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*) 13 MAY 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes
No

Indication POST SEPTOPLASTY
PROPHYLACTIC

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify SPRAY

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

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 24 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication ONDANSETRON

Prophylaxis Yes
No

Indication PROPHYLACTIC

Dose per administration 4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

CONTINUOUS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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*) 22 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 23 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication SODIUM CHLORIDE 0.5%

Prophylaxis Yes
No

Indication PROPHYLACTIC

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

CONTINUOUS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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*) 22 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 23 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication FERROUS SULFATE

Prophylaxis Yes
No

Indication ANEMIA

Dose per administration 325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

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 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 10 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication DOXYCYCLINE

Prophylaxis Yes
No

Indication PROPHYLAXIS SEPTOPLASTY

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 11 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 21 NOV 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Name of Medication OMNIPAQUE

Prophylaxis Yes
No

Indication CTA OF HEAD AND NECK

Dose per administration 350

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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US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>

If route of administration is Other, specify	INJECTION
Start date (<i>dd MMM yyyy</i>)	23 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	23 NOV 2020
Was this medication taken for solicited event?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 <input type="radio"/> 803 <input type="radio"/> 804 <input type="radio"/>

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:35:44

Generated On: 09 Jun 2021 15:35:05

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 19:09:29

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 NOV 2020	EKG	Diagnostic	
11 NOV 2020	SEPTOPLASTY	Medical History	
24 OCT 2020	COVID TEST	Diagnostic	
23 NOV 2020	CT SCAN	Diagnostic	
22 NOV 2020	CT SCAN	Diagnostic	
22 NOV 2020	LABWORK	Diagnostic	
25 NOV 2020	ECHOCARDIOGRAM	Diagnostic	
11 NOV 2020	CHEST X-RAY	Diagnostic	
23 NOV 2020	CTA OF HEAD AND NECK	Diagnostic	

US3182192

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:35:05

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

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P30 1000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P30 1000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	30/NOV/2020 12:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P301000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	04/DEC/2020 14:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P30 1000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/DEC/2020 18:45
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

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P30 1000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/JAN/2021 16:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P301000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	01/MAR/2021 09:38
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

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P30 1000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	05/MAR/2021 11:26
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

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P301000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	26/MAR/2021 10:38
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

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P301000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/APR/2021 13:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P30 1000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	26/APR/2021 16:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (10)

Data signed: (b) (4) 30 Apr 2021 20:37:33

Generated On: 09 Jun 2021 15:35:05

SAEID	USA-US075-2020-MRNA-1273-P30 1000005
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	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	30/APR/2021 06:26
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

US3182192 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182192

Form: Participant Creation

Generated On: 09 Jun 2021 15:35:05

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'US3182192'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:34:36

US3182192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:31:08

US3182192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:34:37

US3182192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	12 Aug 2020 18:31:08

US3182192

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'SCRN'	System	12 Aug 2020 18:31:08

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:34:38

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '63'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'YEARS'	System	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '63'	System	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Female (F)'	Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '1'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:35:05

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:31:36

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '6 Aug 2020'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Aug 2020'	System	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2020'	System	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Amendment 1 (1)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:09:49

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:34:37

US3182192

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:35:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '1'	System	06 Aug 2020 14:09:55

US3182192

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:09:55

US3182192

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:35:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:50

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:38:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:38:11
Data point term sent to Coder	System	12 Aug 2020 18:37:04
User entered 'Moderate Asthma'	Cassie Uminski (b) (4)	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2014'	Cassie Uminski (b) (4)	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2014'	System	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2014'	System	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:37:02

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
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)	12 Aug 2020 18:39:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:39:14
Data point term sent to Coder	System	12 Aug 2020 18:38:04
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4)	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 1960'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 1960'	System	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '1960'	System	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:37:13

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:39:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:39:14
Data point term sent to Coder	System	12 Aug 2020 18:38:06
User entered 'Hypertension'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2000'	Cassie Uminski (b) (4)	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2000'	System	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2000'	System	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:37:26

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Goiter - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:40:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:40:18
Data point term sent to Coder	System	12 Aug 2020 18:39:12
User entered 'Goiter'	Cassie Uminski (b) (4)	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2000'	Cassie Uminski (b) (4)	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2000'	Cassie Uminski (b) (4)	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2000'	System	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2000'	System	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2000'	System	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2000'	System	12 Aug 2020 18:38:24

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Trigeminal disorders, PT: Trigeminal neuralgia, LLT: Trigeminal neuralgia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:40:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:40:19
Data point term sent to Coder	System	12 Aug 2020 18:39:14
User entered 'Trigeminal Neuralgia'	Cassie Uminski (b) (4)	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un Oct 2019'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un Mar 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Oct 2019'	System	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2019'	System	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Mar 2020'	System	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2020'	System	12 Aug 2020 18:38:50

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 05:06:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:22:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:22:42
Data point term sent to Coder	System	10 Sep 2020 15:21:35
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:21:00
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:20:56
User entered 'OSTEOARTHRITIS-Right knee' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:20:56
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 05:56:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:19
Data point term sent to Coder	System	12 Aug 2020 18:39:14
User entered 'Osteoarthritis'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2015'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2015'	System	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2015'	System	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:39:00

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Aug 2020 18:40:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:40:19
Data point term sent to Coder	System	12 Aug 2020 18:39:15
User entered 'Osteopenia'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:14
	(b) (4)	

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2015'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2015'	System	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2015'	System	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:39:14

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:12
Data point term sent to Coder	System	12 Aug 2020 18:40:15
User entered 'Anxiety'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2000'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2000'	System	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2000'	System	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:39:26

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:12
Data point term sent to Coder	System	12 Aug 2020 18:40:16
User entered 'Appendicitis'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2008'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2008'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2008'	System	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2008'	System	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2008'	System	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2008'	System	12 Aug 2020 18:39:41

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:13
Data point term sent to Coder	System	12 Aug 2020 18:40:17
User entered 'Appendectomy'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2008'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2008'	Cassie Uminski (b) (4)	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2008'	System	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2008'	System	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2008'	System	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2008'	System	12 Aug 2020 18:39:59

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:14
Data point term sent to Coder	System	12 Aug 2020 18:40:18
User entered 'Acid Reflux'	Cassie Uminski (b) (4)	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 2009'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2009'	System	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2009'	System	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	12 Aug 2020 18:40:11

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 00:23:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 00:23:32
Data point term sent to Coder	System	01 Mar 2021 00:23:08
User entered 'Deviated Septum'	Jennifer Gaston (b) (4)	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '17 Jan 2018'	(b) (4) Jennifer Gaston (b) (4)	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2018'	System	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2018'	System	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 00:22:54

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 08:09:07
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Updated trelegy' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:36:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:33:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:33:28
Data point term sent to Coder	System	25 Mar 2021 15:33:01
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:32:53
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:32:53
User entered 'Chronic Obstructive Pulmonary Disease' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:32:53
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:21:50
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 00:24:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	01 Mar 2021 00:24:33
Data point term sent to Coder	System	01 Mar 2021 00:24:09
User entered 'COPD'	Jennifer Gaston (b) (4)	01 Mar 2021 00:23:45
	(b) (4)	

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '19 May 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'May 2020'	System	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2020'	System	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 00:23:45

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 00:25:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 00:25:33
Data point term sent to Coder	System	01 Mar 2021 00:25:10
User entered 'GERD'	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'un May 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'May 2020'	System	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2020'	System	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 00:24:12

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 18:43:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 18:43:52
Data point term sent to Coder	System	01 Mar 2021 18:42:50
User entered 'Hemorrhoids'	Cassie Uminski (b) (4)	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'un UNK 2012'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2012'	System	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2012'	System	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 18:41:59

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 18:43:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Mar 2021 18:43:52
Data point term sent to Coder	System	01 Mar 2021 18:42:50
User entered 'Insomnia'	Cassie Uminski (b) (4)	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'un UNK 2019'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '0'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'Jan 2019'	System	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '2019'	System	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered empty.	System	01 Mar 2021 18:42:08

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '06 Aug 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '09:25'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered '06 Aug 2020 09:25'	System	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '164.9' cm	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30
DataPoint set to visible.	(b) (4) System	06 Aug 2020 14:09:55

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '80.1' kg	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30
DataPoint set to visible.	(b) (4) System	06 Aug 2020 14:09:55

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
Amendment Manager: User entered '29.45718'	System	16 Sep 2020 23:45:07
User entered '29.5'	System	12 Aug 2020 18:32:30
DataPoint set to visible.	System	06 Aug 2020 14:09:55

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'kg/m2'	System	12 Aug 2020 18:32:30
DataPoint set to visible.	System	06 Aug 2020 14:09:55

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 05:05:45
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:19:48
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:19:43
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 05:24:15
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'bpm'	System	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'breaths/min'	System	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'mmHg'	System	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User entered 'mmHg'	System	12 Aug 2020 18:32:30

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39

US3182192

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39

US3182192

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:49

US3182192

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 14:36:38
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:16:04
User entered '06 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:34:49

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '06 Aug 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'un UNK 1997'	Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:35:05

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:34:16

US3182192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

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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)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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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)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32
	(b) (4)	

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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)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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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)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered 'Office Manager'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '1'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered '0'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:35:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:17:39
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:42:26
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:36:32

US3182192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:54

US3182192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '06 Aug 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:54

US3182192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[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 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	12 Aug 2020 18:35:54

US3182192

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'VISIT1'	System	12 Aug 2020 18:35:54

US3182192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:50:03

US3182192

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:27:26
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:27:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 13:50:03
User entered '143112' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:50:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:50:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

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 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:34:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

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 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:35:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:37

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '06 Aug 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '09:25'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '06 Aug 2020 09:25'	System	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '98.2' F	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '66'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'bpm'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '16'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'breaths/min'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '150'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '89'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered missing code ND - Not Done.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '06 Aug 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:49:24
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 18:33:48
User entered '10:38'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '06 Aug 2020 10:38'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '98.2' F	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '61'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'bpm'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '14'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'breaths/min'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '117'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '74'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	12 Aug 2020 18:33:48

US3182192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:57
	(b) (4)	

US3182192

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:34:57

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

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 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '6 Aug 2020'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '10:03'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '6 Aug 2020 10:03'	System	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'ONCE'	System	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 14:10:16

US3182192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:43

US3182192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '06 Aug 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:43

US3182192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '09:45'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:43

US3182192

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '06 Aug 2020 09:45'	System	12 Aug 2020 18:35:43

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '06 Aug 2020'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '09:30'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '06 Aug 2020 09:30'	System	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered empty.	System	12 Aug 2020 18:35:17

US3182192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	12 Aug 2020 18:35:26

US3182192

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	12 Aug 2020 18:35:26

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:10:16

tb

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:32:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d9303a9-efb4-4bc5-bbe1-aab56e8b4079' User entered 'Yes (Y)'	System	06 Aug 2020 14:34:42
	System	06 Aug 2020 14:34:42

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:34:27', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d9303a9-efb4-4bc5-bbe1-aab56e8b4079' User entered '98.2'	System	06 Aug 2020 14:34:42
	System	06 Aug 2020 14:34:42

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:34:33', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d9303a9-efb4-4bc5-bbe1-aab56e8b4079' User entered 'No (N)'	System	06 Aug 2020 14:34:42
	System	06 Aug 2020 14:34:42

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:34:40', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d9303a9-efb4-4bc5-bbe1-aab56e8b4079' User entered '06 Aug 2020 10:34'	System	06 Aug 2020 14:34:42
	System	06 Aug 2020 14:34:42

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 10:23'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 12:53'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:08', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6ac49ad7-fa9e-4e2c-9596-f01e96343918' User entered 'Yes (Y)'	System	06 Aug 2020 21:52:30
	System	06 Aug 2020 21:52:30

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:15', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6ac49ad7-fa9e-4e2c-9596-f01e96343918' User entered '96.5'	System	06 Aug 2020 21:52:30
	System	06 Aug 2020 21:52:30

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6ac49ad7-fa9e-4e2c-9596-f01e96343918'	System	06 Aug 2020 21:52:30
User entered 'No (N)'	System	06 Aug 2020 21:52:30

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:28', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6ac49ad7-fa9e-4e2c-9596-f01e96343918' User entered '06 Aug 2020 17:52'	System	06 Aug 2020 21:52:30
	System	06 Aug 2020 21:52:30

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 13:48'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 2'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:07', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5941285e-f3f4-4d8b-acc1-f60dd995f502'	System	07 Aug 2020 16:24:37
User entered 'Yes (Y)'	System	07 Aug 2020 16:24:37

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:14', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5941285e-f3f4-4d8b-acc1-f60dd995f502'	System	07 Aug 2020 16:24:37
User entered '97.9'	System	07 Aug 2020 16:24:37

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:31', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5941285e-f3f4-4d8b-acc1-f60dd995f502'	System	07 Aug 2020 16:24:37
User entered 'No (N)'	System	07 Aug 2020 16:24:37

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:35', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5941285e-f3f4-4d8b-acc1-f60dd995f502' User entered '07 Aug 2020 12:24'	System	07 Aug 2020 16:24:37
	System	07 Aug 2020 16:24:37

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 3'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:25', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e7d03d1a-2022-46f9-972e-d8420dedaae5'	System	08 Aug 2020 22:01:44
User entered 'Yes (Y)'	System	08 Aug 2020 22:01:44

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e7d03d1a-2022-46f9-972e-d8420dedaae5' User entered '96.8'	System	08 Aug 2020 22:01:44
	System	08 Aug 2020 22:01:44

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e7d03d1a-2022-46f9-972e-d8420dedaae5'	System	08 Aug 2020 22:01:44
User entered 'No (N)'	System	08 Aug 2020 22:01:44

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:40', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e7d03d1a-2022-46f9-972e-d8420dedaae5' User entered '08 Aug 2020 18:01'	System	08 Aug 2020 22:01:44
	System	08 Aug 2020 22:01:44

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 4'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:17:43', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '115aba0b-6b98-41a5-88e4-697580f5b6bb' User entered 'Yes (Y)'	System	09 Aug 2020 22:18:02
	System	09 Aug 2020 22:18:02

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:17:49', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '115aba0b-6b98-41a5-88e4-697580f5b6bb' User entered '97.6'	System	09 Aug 2020 22:18:02
	System	09 Aug 2020 22:18:02

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:17:54', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '115aba0b-6b98-41a5-88e4-697580f5b6bb'	System	09 Aug 2020 22:18:02
User entered 'No (N)'	System	09 Aug 2020 22:18:02

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '115aba0b-6b98-41a5-88e4-697580f5b6bb' User entered '09 Aug 2020 18:18'	System	09 Aug 2020 22:18:02
	System	09 Aug 2020 22:18:02

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 5'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:44:40', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1e89a7b3-620f-4e3a-89f7-46e9c195feb1' User entered 'Yes (Y)'	System	10 Aug 2020 22:44:57
	System	10 Aug 2020 22:44:57

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:44:46', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1e89a7b3-620f-4e3a-89f7-46e9c195feb1' User entered '97.9'	System	10 Aug 2020 22:44:57
	System	10 Aug 2020 22:44:57

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:44:50', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1e89a7b3-620f-4e3a-89f7-46e9c195feb1' User entered 'No (N)'	System	10 Aug 2020 22:44:57
	System	10 Aug 2020 22:44:57

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:44:54', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1e89a7b3-620f-4e3a-89f7-46e9c195feb1' User entered '10 Aug 2020 18:44'	System	10 Aug 2020 22:44:57
	System	10 Aug 2020 22:44:57

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 6'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:14', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '565c445b-c0d4-488b-bad8-199de982aca9' User entered 'Yes (Y)'	System	11 Aug 2020 21:31:33
	System	11 Aug 2020 21:31:33

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:20', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '565c445b-c0d4-488b-bad8-199de982aca9' User entered '97.1'	System	11 Aug 2020 21:31:33
	System	11 Aug 2020 21:31:33

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:26', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '565c445b-c0d4-488b-bad8-199de982aca9' User entered 'No (N)'	System	11 Aug 2020 21:31:33
	System	11 Aug 2020 21:31:33

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:29', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '565c445b-c0d4-488b-bad8-199de982aca9' User entered '11 Aug 2020 17:31'	System	11 Aug 2020 21:31:33
	System	11 Aug 2020 21:31:33

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 7'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:12:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '967f539c-4328-4874-946a-93732b027bff' User entered 'Yes (Y)'	System	12 Aug 2020 22:12:41
	System	12 Aug 2020 22:12:41

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:12:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '967f539c-4328-4874-946a-93732b027bff' User entered '96.0'	System	12 Aug 2020 22:12:41
	System	12 Aug 2020 22:12:41

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:12:28', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '967f539c-4328-4874-946a-93732b027bff' User entered 'No (N)'	System	12 Aug 2020 22:12:41
	System	12 Aug 2020 22:12:41

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:12:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '967f539c-4328-4874-946a-93732b027bff' User entered '12 Aug 2020 18:12'	System	12 Aug 2020 22:12:41
	System	12 Aug 2020 22:12:41

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:36:42', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '33c3bafa-636d-456a-86d4-1aae9c6c08ca' User entered 'None (1)'	System	06 Aug 2020 14:37:11
	System	06 Aug 2020 14:37:11

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:36:49', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '33c3bafa-636d-456a-86d4-1aae9c6c08ca' User entered 'No (N)'	System	06 Aug 2020 14:37:11
	System	06 Aug 2020 14:37:11

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:36:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '33c3bafa-636d-456a-86d4-1aae9c6c08ca' User entered 'No (N)'	System	06 Aug 2020 14:37:11
	System	06 Aug 2020 14:37:11

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:04', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '33c3bafa-636d-456a-86d4-1aae9c6c08ca' User entered 'None (1)'	System	06 Aug 2020 14:37:11
	System	06 Aug 2020 14:37:11

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:09', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '33c3bafa-636d-456a-86d4-1aae9c6c08ca' User entered '06 Aug 2020 10:37'	System	06 Aug 2020 14:37:11
	System	06 Aug 2020 14:37:11

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 10:23'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 12:53'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:42', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9588a5c0-8163-4dd3-9c74-fdcab098569e' User entered 'None (1)'	System	06 Aug 2020 21:54:04
	System	06 Aug 2020 21:54:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:45', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9588a5c0-8163-4dd3-9c74-fdcab098569e' User entered 'No (N)'	System	06 Aug 2020 21:54:04
	System	06 Aug 2020 21:54:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:53', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9588a5c0-8163-4dd3-9c74-fdcab098569e' User entered 'No (N)'	System	06 Aug 2020 21:54:04
	System	06 Aug 2020 21:54:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:58', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9588a5c0-8163-4dd3-9c74-fdcab098569e' User entered 'None (1)'	System	06 Aug 2020 21:54:04
	System	06 Aug 2020 21:54:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:54:02', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9588a5c0-8163-4dd3-9c74-fdcab098569e' User entered '06 Aug 2020 17:54'	System	06 Aug 2020 21:54:04
	System	06 Aug 2020 21:54:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 13:48'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 2'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '21c315f1-6657-48f5-ac96-ad41a028d868'	System	07 Aug 2020 16:25:04
User entered 'None (1)'	System	07 Aug 2020 16:25:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:50', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '21c315f1-6657-48f5-ac96-ad41a028d868'	System	07 Aug 2020 16:25:04
User entered 'No (N)'	System	07 Aug 2020 16:25:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:55', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '21c315f1-6657-48f5-ac96-ad41a028d868'	System	07 Aug 2020 16:25:04
User entered 'No (N)'	System	07 Aug 2020 16:25:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:24:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '21c315f1-6657-48f5-ac96-ad41a028d868'	System	07 Aug 2020 16:25:04
User entered 'None (1)'	System	07 Aug 2020 16:25:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:25:02', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '21c315f1-6657-48f5-ac96-ad41a028d868' User entered '07 Aug 2020 12:25'	System	07 Aug 2020 16:25:04
	System	07 Aug 2020 16:25:04

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 3'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:45', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41fee142-2eab-4628-a463-2748236f7abf'	System	08 Aug 2020 22:02:37
User entered 'None (1)'	System	08 Aug 2020 22:02:37

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:49', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41fee142-2eab-4628-a463-2748236f7abf'	System	08 Aug 2020 22:02:37
User entered 'No (N)'	System	08 Aug 2020 22:02:37

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:53', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41fee142-2eab-4628-a463-2748236f7abf'	System	08 Aug 2020 22:02:37
User entered 'No (N)'	System	08 Aug 2020 22:02:37

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:01:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41fee142-2eab-4628-a463-2748236f7abf'	System	08 Aug 2020 22:02:37
User entered 'None (1)'	System	08 Aug 2020 22:02:37

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:01', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41fee142-2eab-4628-a463-2748236f7abf' User entered '08 Aug 2020 18:02'	System	08 Aug 2020 22:02:37
	System	08 Aug 2020 22:02:37

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 4'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:08', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f59f1108-e9e8-4a86-96b0-4a81c0288ae2'	System	09 Aug 2020 22:18:24
User entered 'None (1)'	System	09 Aug 2020 22:18:24

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:11', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f59f1108-e9e8-4a86-96b0-4a81c0288ae2' User entered 'No (N)'	System	09 Aug 2020 22:18:24
	System	09 Aug 2020 22:18:24

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:14', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f59f1108-e9e8-4a86-96b0-4a81c0288ae2' User entered 'No (N)'	System	09 Aug 2020 22:18:24
	System	09 Aug 2020 22:18:24

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f59f1108-e9e8-4a86-96b0-4a81c0288ae2'	System	09 Aug 2020 22:18:24
User entered 'None (1)'	System	09 Aug 2020 22:18:24

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:23', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f59f1108-e9e8-4a86-96b0-4a81c0288ae2' User entered '09 Aug 2020 18:18'	System	09 Aug 2020 22:18:24
	System	09 Aug 2020 22:18:24

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 5'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:44:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b356df96-e0fe-4176-8ce5-7e3f81eca15d' User entered 'None (1)'	System	10 Aug 2020 22:45:15
	System	10 Aug 2020 22:45:15

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:03', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b356df96-e0fe-4176-8ce5-7e3f81eca15d' User entered 'No (N)'	System	10 Aug 2020 22:45:15
	System	10 Aug 2020 22:45:15

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:06', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b356df96-e0fe-4176-8ce5-7e3f81eca15d' User entered 'No (N)'	System	10 Aug 2020 22:45:15
	System	10 Aug 2020 22:45:15

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:09', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b356df96-e0fe-4176-8ce5-7e3f81eca15d' User entered 'None (1)'	System	10 Aug 2020 22:45:15
	System	10 Aug 2020 22:45:15

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:13', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b356df96-e0fe-4176-8ce5-7e3f81eca15d' User entered '10 Aug 2020 18:45'	System	10 Aug 2020 22:45:15
	System	10 Aug 2020 22:45:15

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 6'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b5d67da-c3ee-4923-89c5-fc1ababf3a7c' User entered 'None (1)'	System	11 Aug 2020 21:31:55
	System	11 Aug 2020 21:31:55

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:39', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b5d67da-c3ee-4923-89c5-fc1ababf3a7c' User entered 'No (N)'	System	11 Aug 2020 21:31:55
	System	11 Aug 2020 21:31:55

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:43', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b5d67da-c3ee-4923-89c5-fc1ababf3a7c' User entered 'No (N)'	System	11 Aug 2020 21:31:55
	System	11 Aug 2020 21:31:55

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:48', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b5d67da-c3ee-4923-89c5-fc1ababf3a7c' User entered 'None (1)'	System	11 Aug 2020 21:31:55
	System	11 Aug 2020 21:31:55

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:51', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b5d67da-c3ee-4923-89c5-fc1ababf3a7c' User entered '11 Aug 2020 17:31'	System	11 Aug 2020 21:31:55
	System	11 Aug 2020 21:31:55

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 7'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:08', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e53f41d4-117a-4da2-88ed-2ab91f907ad9' User entered 'None (1)'	System	12 Aug 2020 22:13:26
	System	12 Aug 2020 22:13:26

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:13', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e53f41d4-117a-4da2-88ed-2ab91f907ad9' User entered 'No (N)'	System	12 Aug 2020 22:13:26
	System	12 Aug 2020 22:13:26

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e53f41d4-117a-4da2-88ed-2ab91f907ad9' User entered 'No (N)'	System	12 Aug 2020 22:13:26
	System	12 Aug 2020 22:13:26

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e53f41d4-117a-4da2-88ed-2ab91f907ad9' User entered 'None (1)'	System	12 Aug 2020 22:13:26
	System	12 Aug 2020 22:13:26

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:23', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e53f41d4-117a-4da2-88ed-2ab91f907ad9' User entered '12 Aug 2020 18:13'	System	12 Aug 2020 22:13:26
	System	12 Aug 2020 22:13:26

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:29', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079' User entered 'None (0)'	System	06 Aug 2020 14:38:03
	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:33', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079' User entered 'None (0)'	System	06 Aug 2020 14:38:03
	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079' User entered 'None (0)'	System	06 Aug 2020 14:38:03
	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:40', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079' User entered 'None (0)'	System	06 Aug 2020 14:38:03
	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:42', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079' User entered 'None (0)'	System	06 Aug 2020 14:38:03
	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:45', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079' User entered 'None (0)'	System	06 Aug 2020 14:38:03
	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:54', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079'	System	06 Aug 2020 14:38:03
User entered 'No (N)'	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T10:37:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21ab554-f328-48de-824c-850ea1d3c079' User entered '06 Aug 2020 10:37'	System	06 Aug 2020 14:38:03
	System	06 Aug 2020 14:38:03

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 10:23'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 12:53'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:46', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered 'None (0)'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:51', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered 'None (0)'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:55', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered 'None (0)'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:52:58', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered 'None (0)'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:01', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered 'None (0)'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:05', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered 'None (0)'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:15', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered 'No (N)'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-06T17:53:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7b315457-330b-4b8b-8911-d013c64a94b9'	System	06 Aug 2020 21:53:22
User entered '06 Aug 2020 17:53'	System	06 Aug 2020 21:53:22

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Aug 2020 13:48'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 2'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:25:09', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c' User entered 'None (0)'	System	07 Aug 2020 16:26:10
	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:25:15', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c' User entered 'None (0)'	System	07 Aug 2020 16:26:10
	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:25:18', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c' User entered 'None (0)'	System	07 Aug 2020 16:26:10
	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:25:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c' User entered 'None (0)'	System	07 Aug 2020 16:26:10
	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:25:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c' User entered 'None (0)'	System	07 Aug 2020 16:26:10
	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:25:28', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c' User entered 'None (0)'	System	07 Aug 2020 16:26:10
	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:26:03', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c'	System	07 Aug 2020 16:26:10
User entered 'No (N)'	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-07T12:26:07', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b13651c9-3d2f-4e1e-b44b-d099b8bb4b6c' User entered '07 Aug 2020 12:26'	System	07 Aug 2020 16:26:10
	System	07 Aug 2020 16:26:10

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 3'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:08', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884' User entered 'None (0)'	System	08 Aug 2020 22:03:13
	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:14', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884'	System	08 Aug 2020 22:03:13
User entered 'None (0)'	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:18', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884' User entered 'None (0)'	System	08 Aug 2020 22:03:13
	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884' User entered 'None (0)'	System	08 Aug 2020 22:03:13
	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884'	System	08 Aug 2020 22:03:13
User entered 'None (0)'	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:28', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884' User entered 'None (0)'	System	08 Aug 2020 22:03:13
	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884'	System	08 Aug 2020 22:03:13
User entered 'No (N)'	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-08T18:02:35', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9fa53789-1dcf-4faf-aba1-c7f742463884' User entered '08 Aug 2020 18:02'	System	08 Aug 2020 22:03:13
	System	08 Aug 2020 22:03:13

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 4'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:29', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5'	System	09 Aug 2020 22:18:59
User entered 'None (0)'	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5'	System	09 Aug 2020 22:18:59
User entered 'None (0)'	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5' User entered 'None (0)'	System	09 Aug 2020 22:18:59
	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:40', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5' User entered 'None (0)'	System	09 Aug 2020 22:18:59
	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:43', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5'	System	09 Aug 2020 22:18:59
User entered 'None (0)'	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5' User entered 'None (0)'	System	09 Aug 2020 22:18:59
	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:55', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5' User entered 'No (N)'	System	09 Aug 2020 22:18:59
	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-09T18:18:58', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7a20467e-1d8b-4c6d-8826-9fbd27e43df5' User entered '09 Aug 2020 18:18'	System	09 Aug 2020 22:18:59
	System	09 Aug 2020 22:18:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 5'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered 'None (0)'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered 'None (0)'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered 'None (0)'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:26', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered 'None (0)'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:28', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered 'None (0)'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered 'None (0)'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:41', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered 'No (N)'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-10T18:45:45', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '357d2637-eedd-49e4-ac1c-803cd329a6f0' User entered '10 Aug 2020 18:45'	System	10 Aug 2020 22:45:49
	System	10 Aug 2020 22:45:49

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 6'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:31:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered 'None (0)'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:32:01', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered 'None (0)'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:32:04', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered 'None (0)'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:32:07', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered 'None (0)'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:32:10', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered 'None (0)'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:32:13', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered 'None (0)'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:32:17', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered 'No (N)'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-11T17:32:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9b5e0293-e9c8-4195-89e2-31df808b176b' User entered '11 Aug 2020 17:32'	System	11 Aug 2020 21:32:24
	System	11 Aug 2020 21:32:24

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 7'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered 'None (0)'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:38', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered 'None (0)'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:41', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered 'None (0)'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered 'None (0)'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:46', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered 'None (0)'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:49', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered 'None (0)'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:53', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered 'No (N)'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-08-12T18:13:56', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8e50d78e-0132-4fa3-9752-7abdb61e64ac' User entered '12 Aug 2020 18:13'	System	12 Aug 2020 22:13:59
	System	12 Aug 2020 22:13:59

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:10:16

US3182192

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:25:57

US3182192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered '13 Aug 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:25:57

US3182192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:25:57

US3182192

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:25:57

US3182192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	20 Aug 2020 14:26:04

US3182192

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	20 Aug 2020 14:26:04

US3182192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:14:03

US3182192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered '20 Aug 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:14:03

US3182192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:14:03

US3182192

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:14:03

US3182192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Aug 2020 13:14:09

US3182192

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	24 Aug 2020 13:14:09

US3182192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	27 Aug 2020 17:27:42

US3182192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered '27 Aug 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	27 Aug 2020 17:27:42

US3182192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	27 Aug 2020 17:27:42

US3182192

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	27 Aug 2020 17:27:42

US3182192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	27 Aug 2020 17:27:45

US3182192

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	27 Aug 2020 17:27:45

US3182192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:16:04

US3182192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '03 Sep 2020'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:16:04

US3182192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[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 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	10 Sep 2020 15:16:04

US3182192

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'VISIT2'	System	10 Sep 2020 15:16:04

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '03 Sep 2020'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33
	(b) (4)	

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '09:19'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33
	(b) (4)	

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '03 Sep 2020 09:19'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '97.8' F	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '66'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'bpm'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '14'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'breaths/min'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '111'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '74'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '03 Sep 2020'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33
	(b) (4)	

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '10:40'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33
	(b) (4)	

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '03 Sep 2020 10:40'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '97.5' F	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '58'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'bpm'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '14'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'breaths/min'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '103'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '67'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'mmHg'	System	10 Sep 2020 15:18:33

US3182192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Sep 2020 15:18:46

US3182192

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '03 Sep 2020'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:18:46
	(b) (4)	

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Brooke Glivar (b) (4) (b) (4)	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

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 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	Brooke Glivar (b) (4)	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '3 Sep 2020'	(b) (4) Brooke Glivar (b) (4) (b) (4)	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '10:05'	(b) (4) Brooke Glivar (b) (4) (b) (4)	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '3 Sep 2020 10:05'	System	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Left Arm (LEFT ARM)'	Brooke Glivar (b) (4)	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'ONCE'	System	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 14:36:43

US3182192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:18

US3182192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '03 Sep 2020'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:18

US3182192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '09:40'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:18

US3182192

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '03 Sep 2020 09:40'	System	10 Sep 2020 15:19:18

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '03 Sep 2020'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '09:30'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:35:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '03 Sep 2020 09:30'	System	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:35:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered empty.	System	10 Sep 2020 15:19:03

US3182192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	10 Sep 2020 15:19:26

US3182192

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	10 Sep 2020 15:19:26

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:37:48', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f4df27db-7c53-4db3-b417-c21a3eb12ad2'	System	03 Sep 2020 14:38:12
User entered 'Yes (Y)'	System	03 Sep 2020 14:38:12

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:37:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f4df27db-7c53-4db3-b417-c21a3eb12ad2' User entered '97.5'	System	03 Sep 2020 14:38:12
	System	03 Sep 2020 14:38:12

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:05', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f4df27db-7c53-4db3-b417-c21a3eb12ad2'	System	03 Sep 2020 14:38:12
User entered 'No (N)'	System	03 Sep 2020 14:38:12

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:11', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f4df27db-7c53-4db3-b417-c21a3eb12ad2' User entered '03 Sep 2020 10:38'	System	03 Sep 2020 14:38:12
	System	03 Sep 2020 14:38:12

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 10:25'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 12:55'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:09:23', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b1dbc276-e277-42b6-83a0-90c757c56b87'	System	03 Sep 2020 23:09:45
User entered 'Yes (Y)'	System	03 Sep 2020 23:09:45

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:09:31', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b1dbc276-e277-42b6-83a0-90c757c56b87' User entered '97.9'	System	03 Sep 2020 23:09:45
	System	03 Sep 2020 23:09:45

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:09:35', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b1dbc276-e277-42b6-83a0-90c757c56b87'	System	03 Sep 2020 23:09:45
User entered 'No (N)'	System	03 Sep 2020 23:09:45

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:09:39', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b1dbc276-e277-42b6-83a0-90c757c56b87'	System	03 Sep 2020 23:09:45
User entered '03 Sep 2020 19:09'	System	03 Sep 2020 23:09:45

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 13:50'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 2'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:15:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5c6e10dd-0f87-4040-abd6-35b11da9c1a3'	System	05 Sep 2020 01:15:47
User entered 'Yes (Y)'	System	05 Sep 2020 01:15:47

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:15:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5c6e10dd-0f87-4040-abd6-35b11da9c1a3' User entered '97.9'	System	05 Sep 2020 01:15:47
	System	05 Sep 2020 01:15:47

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:15:39', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5c6e10dd-0f87-4040-abd6-35b11da9c1a3'	System	05 Sep 2020 01:15:47
User entered 'No (N)'	System	05 Sep 2020 01:15:47

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:15:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5c6e10dd-0f87-4040-abd6-35b11da9c1a3'	System	05 Sep 2020 01:15:47
User entered '04 Sep 2020 21:15'	System	05 Sep 2020 01:15:47

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 3'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:29:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '78c80c5d-b40c-4d56-bb38-e6696151202c'	System	05 Sep 2020 21:30:04
User entered 'Yes (Y)'	System	05 Sep 2020 21:30:04

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:29:53', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '78c80c5d-b40c-4d56-bb38-e6696151202c' User entered '97.2'	System	05 Sep 2020 21:30:04
	System	05 Sep 2020 21:30:04

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:29:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '78c80c5d-b40c-4d56-bb38-e6696151202c'	System	05 Sep 2020 21:30:04
User entered 'No (N)'	System	05 Sep 2020 21:30:04

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '78c80c5d-b40c-4d56-bb38-e6696151202c' User entered '05 Sep 2020 17:30'	System	05 Sep 2020 21:30:04
	System	05 Sep 2020 21:30:04

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 4'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:20', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '2803c666-eb7a-41e1-aa6e-ff2db732945b' User entered 'Yes (Y)'	System	06 Sep 2020 23:54:39
	System	06 Sep 2020 23:54:39

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:27', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '2803c666-eb7a-41e1-aa6e-ff2db732945b' User entered '97.9'	System	06 Sep 2020 23:54:39
	System	06 Sep 2020 23:54:39

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '2803c666-eb7a-41e1-aa6e-ff2db732945b'	System	06 Sep 2020 23:54:39
User entered 'No (N)'	System	06 Sep 2020 23:54:39

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '2803c666-eb7a-41e1-aa6e-ff2db732945b' User entered '06 Sep 2020 19:54'	System	06 Sep 2020 23:54:39
	System	06 Sep 2020 23:54:39

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 5'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:05', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '55a784ae-c0cb-4287-b4c4-fd23000b2d60'	System	08 Sep 2020 01:19:35
User entered 'Yes (Y)'	System	08 Sep 2020 01:19:35

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '55a784ae-c0cb-4287-b4c4-fd23000b2d60' User entered '97.6'	System	08 Sep 2020 01:19:35
	System	08 Sep 2020 01:19:35

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:27', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '55a784ae-c0cb-4287-b4c4-fd23000b2d60'	System	08 Sep 2020 01:19:35
User entered 'No (N)'	System	08 Sep 2020 01:19:35

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '55a784ae-c0cb-4287-b4c4-fd23000b2d60' User entered '07 Sep 2020 21:19'	System	08 Sep 2020 01:19:35
	System	08 Sep 2020 01:19:35

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 6'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c4938174-18f3-4936-ae25-ac1a02181c4f' User entered 'Yes (Y)'	System	08 Sep 2020 23:57:41
	System	08 Sep 2020 23:57:41

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c4938174-18f3-4936-ae25-ac1a02181c4f' User entered '97.5'	System	08 Sep 2020 23:57:41
	System	08 Sep 2020 23:57:41

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:35', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c4938174-18f3-4936-ae25-ac1a02181c4f'	System	08 Sep 2020 23:57:41
User entered 'No (N)'	System	08 Sep 2020 23:57:41

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:39', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c4938174-18f3-4936-ae25-ac1a02181c4f' User entered '08 Sep 2020 19:57'	System	08 Sep 2020 23:57:41
	System	08 Sep 2020 23:57:41

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 7'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:17:49', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '13f7238a-8cf0-4008-9884-a2dc7da0e8d6'	System	09 Sep 2020 23:18:10
User entered 'Yes (Y)'	System	09 Sep 2020 23:18:10

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:17:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '13f7238a-8cf0-4008-9884-a2dc7da0e8d6' User entered '97.9'	System	09 Sep 2020 23:18:10
	System	09 Sep 2020 23:18:10

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '13f7238a-8cf0-4008-9884-a2dc7da0e8d6'	System	09 Sep 2020 23:18:10
User entered 'No (N)'	System	09 Sep 2020 23:18:10

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:07', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '13f7238a-8cf0-4008-9884-a2dc7da0e8d6' User entered '09 Sep 2020 19:18'	System	09 Sep 2020 23:18:10
	System	09 Sep 2020 23:18:10

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5626a716-af63-40ab-91bb-b0c8c6dbb952'	System	03 Sep 2020 14:38:48
User entered 'None (1)'	System	03 Sep 2020 14:38:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:31', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5626a716-af63-40ab-91bb-b0c8c6d952'	System	03 Sep 2020 14:38:48
User entered 'No (N)'	System	03 Sep 2020 14:38:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5626a716-af63-40ab-91bb-b0c8c6dbb952'	System	03 Sep 2020 14:38:48
User entered 'No (N)'	System	03 Sep 2020 14:38:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:42', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5626a716-af63-40ab-91bb-b0c8c6dbb952'	System	03 Sep 2020 14:38:48
User entered 'None (1)'	System	03 Sep 2020 14:38:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:45', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5626a716-af63-40ab-91bb-b0c8c6dbb952'	System	03 Sep 2020 14:38:48
User entered '03 Sep 2020 10:38'	System	03 Sep 2020 14:38:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 10:25'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 12:55'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:09:48', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5cd863e6-7a1a-4f2e-977f-ead5fa3abb72'	System	03 Sep 2020 23:10:07
User entered 'None (1)'	System	03 Sep 2020 23:10:07

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:09:52', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5cd863e6-7a1a-4f2e-977f-ead5fa3abb72'	System	03 Sep 2020 23:10:07
User entered 'No (N)'	System	03 Sep 2020 23:10:07

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:09:56', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5cd863e6-7a1a-4f2e-977f-ead5fa3abb72'	System	03 Sep 2020 23:10:07
User entered 'No (N)'	System	03 Sep 2020 23:10:07

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5cd863e6-7a1a-4f2e-977f-ead5fa3abb72'	System	03 Sep 2020 23:10:07
User entered 'None (1)'	System	03 Sep 2020 23:10:07

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:05', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '5cd863e6-7a1a-4f2e-977f-ead5fa3abb72'	System	03 Sep 2020 23:10:07
User entered '03 Sep 2020 19:10'	System	03 Sep 2020 23:10:07

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 13:50'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 2'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:15:50', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b50dcded-9987-4805-92ab-af9bf1bd60cc'	System	05 Sep 2020 01:16:09
User entered 'None (1)'	System	05 Sep 2020 01:16:09

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:15:55', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b50dcded-9987-4805-92ab-af9bf1bd60cc'	System	05 Sep 2020 01:16:09
User entered 'No (N)'	System	05 Sep 2020 01:16:09

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:15:58', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b50dcded-9987-4805-92ab-af9bf1bd60cc'	System	05 Sep 2020 01:16:09
User entered 'No (N)'	System	05 Sep 2020 01:16:09

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:03', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b50dcded-9987-4805-92ab-af9bf1bd60cc'	System	05 Sep 2020 01:16:09
User entered 'None (1)'	System	05 Sep 2020 01:16:09

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:06', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'b50dcded-9987-4805-92ab-af9bf1bd60cc' User entered '04 Sep 2020 21:16'	System	05 Sep 2020 01:16:09
	System	05 Sep 2020 01:16:09

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 3'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:07', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bbf29853-b493-4629-a404-87e3d1f3f00c'	System	05 Sep 2020 21:30:20
User entered 'None (1)'	System	05 Sep 2020 21:30:20

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:10', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bbf29853-b493-4629-a404-87e3d1f3f00c'	System	05 Sep 2020 21:30:20
User entered 'No (N)'	System	05 Sep 2020 21:30:20

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:13', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bbf29853-b493-4629-a404-87e3d1f3f00c'	System	05 Sep 2020 21:30:20
User entered 'No (N)'	System	05 Sep 2020 21:30:20

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bbf29853-b493-4629-a404-87e3d1f3f00c'	System	05 Sep 2020 21:30:20
User entered 'None (1)'	System	05 Sep 2020 21:30:20

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:18', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bbf29853-b493-4629-a404-87e3d1f3f00c' User entered '05 Sep 2020 17:30'	System	05 Sep 2020 21:30:20
	System	05 Sep 2020 21:30:20

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 4'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:41', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8aa0db14-3ad4-4e42-8d47-84109356b3a5'	System	06 Sep 2020 23:54:55
User entered 'None (1)'	System	06 Sep 2020 23:54:55

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8aa0db14-3ad4-4e42-8d47-84109356b3a5'	System	06 Sep 2020 23:54:55
User entered 'No (N)'	System	06 Sep 2020 23:54:55

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8aa0db14-3ad4-4e42-8d47-84109356b3a5'	System	06 Sep 2020 23:54:55
User entered 'No (N)'	System	06 Sep 2020 23:54:55

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:50', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8aa0db14-3ad4-4e42-8d47-84109356b3a5'	System	06 Sep 2020 23:54:55
User entered 'None (1)'	System	06 Sep 2020 23:54:55

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:54', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8aa0db14-3ad4-4e42-8d47-84109356b3a5'	System	06 Sep 2020 23:54:55
User entered '06 Sep 2020 19:54'	System	06 Sep 2020 23:54:55

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 5'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:36', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c780103-64ad-4d7a-8084-d7c8d7776b22'	System	08 Sep 2020 01:19:48
User entered 'None (1)'	System	08 Sep 2020 01:19:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:39', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c780103-64ad-4d7a-8084-d7c8d7776b22'	System	08 Sep 2020 01:19:48
User entered 'No (N)'	System	08 Sep 2020 01:19:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:41', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c780103-64ad-4d7a-8084-d7c8d7776b22'	System	08 Sep 2020 01:19:48
User entered 'No (N)'	System	08 Sep 2020 01:19:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c780103-64ad-4d7a-8084-d7c8d7776b22'	System	08 Sep 2020 01:19:48
User entered 'None (1)'	System	08 Sep 2020 01:19:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:46', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c780103-64ad-4d7a-8084-d7c8d7776b22'	System	08 Sep 2020 01:19:48
User entered '07 Sep 2020 21:19'	System	08 Sep 2020 01:19:48

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 6'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '4c84eb06-d97a-4f8b-9c74-cc7f52b54835'	System	08 Sep 2020 23:58:02
User entered 'None (1)'	System	08 Sep 2020 23:58:02

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '4c84eb06-d97a-4f8b-9c74-cc7f52b54835'	System	08 Sep 2020 23:58:02
User entered 'No (N)'	System	08 Sep 2020 23:58:02

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:51', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '4c84eb06-d97a-4f8b-9c74-cc7f52b54835'	System	08 Sep 2020 23:58:02
User entered 'No (N)'	System	08 Sep 2020 23:58:02

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:56', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '4c84eb06-d97a-4f8b-9c74-cc7f52b54835'	System	08 Sep 2020 23:58:02
User entered 'None (1)'	System	08 Sep 2020 23:58:02

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:57:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '4c84eb06-d97a-4f8b-9c74-cc7f52b54835' User entered '08 Sep 2020 19:57'	System	08 Sep 2020 23:58:02
	System	08 Sep 2020 23:58:02

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 7'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:12', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d8ce577-92aa-40a5-9a8e-4a41c5b13b75'	System	09 Sep 2020 23:18:29
User entered 'None (1)'	System	09 Sep 2020 23:18:29

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d8ce577-92aa-40a5-9a8e-4a41c5b13b75'	System	09 Sep 2020 23:18:29
User entered 'No (N)'	System	09 Sep 2020 23:18:29

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d8ce577-92aa-40a5-9a8e-4a41c5b13b75' User entered 'No (N)'	System	09 Sep 2020 23:18:29
	System	09 Sep 2020 23:18:29

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d8ce577-92aa-40a5-9a8e-4a41c5b13b75'	System	09 Sep 2020 23:18:29
User entered 'None (1)'	System	09 Sep 2020 23:18:29

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:25', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '9d8ce577-92aa-40a5-9a8e-4a41c5b13b75' User entered '09 Sep 2020 19:18'	System	09 Sep 2020 23:18:29
	System	09 Sep 2020 23:18:29

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:51', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4' User entered 'None (0)'	System	03 Sep 2020 14:39:25
	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:54', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4' User entered 'None (0)'	System	03 Sep 2020 14:39:25
	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:38:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4' User entered 'None (0)'	System	03 Sep 2020 14:39:25
	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:39:03', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4' User entered 'None (0)'	System	03 Sep 2020 14:39:25
	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:39:06', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4'	System	03 Sep 2020 14:39:25
User entered 'None (0)'	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:39:09', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4' User entered 'None (0)'	System	03 Sep 2020 14:39:25
	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:39:17', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4'	System	03 Sep 2020 14:39:25
User entered 'No (N)'	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T10:39:20', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '83dca423-50c1-4897-aace-e4ad55d69da4' User entered '03 Sep 2020 10:39'	System	03 Sep 2020 14:39:25
	System	03 Sep 2020 14:39:25

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 10:25'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 12:55'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:10', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered 'None (0)'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:15', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered 'None (0)'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered 'None (0)'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:22', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered 'None (0)'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered 'None (0)'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:27', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered 'None (0)'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:31', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered 'No (N)'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-03T19:10:35', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd7a0dcb4-68c1-4b9b-873a-15a1e03fe051' User entered '03 Sep 2020 19:10'	System	03 Sep 2020 23:10:37
	System	03 Sep 2020 23:10:37

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '03 Sep 2020 13:50'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 2'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:12', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384' User entered 'None (0)'	System	05 Sep 2020 01:16:45
	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:17', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384' User entered 'None (0)'	System	05 Sep 2020 01:16:45
	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:20', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384' User entered 'None (0)'	System	05 Sep 2020 01:16:45
	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384' User entered 'None (0)'	System	05 Sep 2020 01:16:45
	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:28', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384'	System	05 Sep 2020 01:16:45
User entered 'None (0)'	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:31', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384' User entered 'None (0)'	System	05 Sep 2020 01:16:45
	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:40', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384'	System	05 Sep 2020 01:16:45
User entered 'No (N)'	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-04T21:16:43', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '764f37dd-6407-4755-9dca-214f24691384'	System	05 Sep 2020 01:16:45
User entered '04 Sep 2020 21:16'	System	05 Sep 2020 01:16:45

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 3'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38'	System	05 Sep 2020 21:30:46
User entered 'None (0)'	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:26', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38'	System	05 Sep 2020 21:30:46
User entered 'None (0)'	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:30', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38' User entered 'None (0)'	System	05 Sep 2020 21:30:46
	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38' User entered 'None (0)'	System	05 Sep 2020 21:30:46
	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:35', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38' User entered 'None (0)'	System	05 Sep 2020 21:30:46
	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:37', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38' User entered 'None (0)'	System	05 Sep 2020 21:30:46
	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:41', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38'	System	05 Sep 2020 21:30:46
User entered 'No (N)'	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-05T17:30:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'd8a9010c-ce06-4fb7-aedf-7aa0922f4f38'	System	05 Sep 2020 21:30:46
User entered '05 Sep 2020 17:30'	System	05 Sep 2020 21:30:46

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 4'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:54:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered 'None (0)'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:55:02', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered 'None (0)'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:55:04', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered 'None (0)'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:55:07', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered 'None (0)'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:55:12', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered 'None (0)'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:55:14', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered 'None (0)'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:55:17', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered 'No (N)'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-06T19:55:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '27a30478-e318-4764-8de8-f6dcb6dec7bd' User entered '06 Sep 2020 19:55'	System	06 Sep 2020 23:55:23
	System	06 Sep 2020 23:55:23

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 5'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:50', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered 'None (0)'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:52', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered 'None (0)'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:55', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered 'None (0)'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered 'None (0)'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:19:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered 'None (0)'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:20:01', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered 'None (0)'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:20:08', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered 'No (N)'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-07T21:20:12', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '222ebc2d-7440-4272-a8f0-f6e0ddca0650' User entered '07 Sep 2020 21:20'	System	08 Sep 2020 01:20:15
	System	08 Sep 2020 01:20:15

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 6'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:04', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249' User entered 'None (0)'	System	08 Sep 2020 23:58:29
	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:07', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249' User entered 'None (0)'	System	08 Sep 2020 23:58:29
	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:10', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249' User entered 'None (0)'	System	08 Sep 2020 23:58:29
	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:13', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249' User entered 'None (0)'	System	08 Sep 2020 23:58:29
	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:15', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249'	System	08 Sep 2020 23:58:29
User entered 'None (0)'	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:18', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249' User entered 'None (0)'	System	08 Sep 2020 23:58:29
	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249'	System	08 Sep 2020 23:58:29
User entered 'No (N)'	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-08T19:58:24', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cc0fc8b5-8f17-4649-9ff4-19e26b665249' User entered '08 Sep 2020 19:58'	System	08 Sep 2020 23:58:29
	System	08 Sep 2020 23:58:29

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	03 Sep 2020 14:36:43
User entered 'Day 7'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:33', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered 'None (0)'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:37', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered 'None (0)'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:39', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered 'None (0)'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:42', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered 'None (0)'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered 'None (0)'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered 'None (0)'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:51', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered 'No (N)'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-09-09T19:18:54', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '90e25bd1-7523-417b-bbcd-53010375d19a'	System	09 Sep 2020 23:18:56
User entered '09 Sep 2020 19:18'	System	09 Sep 2020 23:18:56

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 14:36:43

US3182192

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:35:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 14:36:43

US3182192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	11 Sep 2020 17:45:55

US3182192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered '10 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	11 Sep 2020 17:45:55

US3182192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	11 Sep 2020 17:45:55

US3182192

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	11 Sep 2020 17:45:55

US3182192

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:20:32
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	11 Sep 2020 17:45:45

US3182192

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	11 Sep 2020 17:45:45

US3182192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:50:38

US3182192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '17 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:50:38

US3182192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:50:38

US3182192

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:50:38

US3182192

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:50:30

US3182192

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	24 Sep 2020 15:50:30

US3182192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Sep 2020 15:57:10

US3182192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '24 Sep 2020'	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Sep 2020 15:57:10

US3182192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Sep 2020 15:57:10

US3182192

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Sep 2020 15:57:10

US3182192

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Alec Ireland (b) (4) (b) (4)	25 Sep 2020 15:57:03

US3182192

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	25 Sep 2020 15:57:03

US3182192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Oct 2020 19:44:23

US3182192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '01 Oct 2020'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:23

US3182192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[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 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Oct 2020 19:44:23

US3182192

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User entered 'VISIT3'	System	07 Oct 2020 19:44:23

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '01 Oct 2020'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '08:58'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:38
	(b) (4)	

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User entered '01 Oct 2020 08:58'	System	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '97.7' F	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:38
	(b) (4)	

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '72'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User entered 'bpm'	System	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User entered 'breaths/min'	System	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '115'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User entered 'mmHg'	System	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '77'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44
User entered 'mmHg'	System	07 Oct 2020 19:44:38

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44

US3182192

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:44

US3182192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:49
	(b) (4)	

US3182192

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered empty.	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:44:49

US3182192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:45:14

US3182192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '01 Oct 2020'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:45:14

US3182192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered '09:00'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Oct 2020 19:45:14

US3182192

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '01 Oct 2020 09:00'	System	07 Oct 2020 19:45:14

US3182192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:15:15
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	07 Oct 2020 19:45:19

US3182192

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered '1'	System	07 Oct 2020 19:45:19

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 64'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-08T13:39:05', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '2a921933-a168-4236-a873-78961a7b4bf2'	System	08 Oct 2020 17:39:32
User entered 'No (N)'	System	08 Oct 2020 17:39:32

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-08T13:39:17', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '2a921933-a168-4236-a873-78961a7b4bf2'	System	08 Oct 2020 17:39:32
User entered 'No (N)'	System	08 Oct 2020 17:39:32

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-08T13:39:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '2a921933-a168-4236-a873-78961a7b4bf2' User entered '08 Oct 2020 13:39:21'	System	08 Oct 2020 17:39:32
	System	08 Oct 2020 17:39:32

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 71'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-15T12:12:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '39a49ed9-bec3-4c31-9210-89ab91f1fa60'	System	15 Oct 2020 16:13:01
User entered 'No (N)'	System	15 Oct 2020 16:13:01

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-15T12:12:55', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '39a49ed9-bec3-4c31-9210-89ab91f1fa60'	System	15 Oct 2020 16:13:01
User entered 'No (N)'	System	15 Oct 2020 16:13:01

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-15T12:12:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '39a49ed9-bec3-4c31-9210-89ab91f1fa60' User entered '15 Oct 2020 12:12:59'	System	15 Oct 2020 16:13:01
	System	15 Oct 2020 16:13:01

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 78'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-20T09:43:06', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6eff0c2b-75ce-4320-90ef-ea45faeb9240' User entered 'No (N)'	System	20 Oct 2020 13:43:23
	System	20 Oct 2020 13:43:23

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-20T09:43:15', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6eff0c2b-75ce-4320-90ef-ea45faeb9240'	System	20 Oct 2020 13:43:23
User entered 'No (N)'	System	20 Oct 2020 13:43:23

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-10-20T09:43:18', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6eff0c2b-75ce-4320-90ef-ea45faeb9240' User entered '20 Oct 2020 09:43:18'	System	20 Oct 2020 13:43:23
	System	20 Oct 2020 13:43:23

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 92'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-03T00:22:58', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e5257d9c-2fbd-4585-937f-ba0f6155195c'	System	03 Nov 2020 05:23:28
User entered 'No (N)'	System	03 Nov 2020 05:23:28

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-03T00:23:10', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e5257d9c-2fbd-4585-937f-ba0f6155195c'	System	03 Nov 2020 05:23:28
User entered 'No (N)'	System	03 Nov 2020 05:23:28

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-03T00:23:25', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'e5257d9c-2fbd-4585-937f-ba0f6155195c' User entered '03 Nov 2020 00:23:25'	System	03 Nov 2020 05:23:28
	System	03 Nov 2020 05:23:28

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 99'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-10T15:45:49', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bc1c022b-67f0-41ae-9f10-5aa8afa2309f' User entered 'No (N)'	System	10 Nov 2020 20:46:11
	System	10 Nov 2020 20:46:11

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-10T15:45:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bc1c022b-67f0-41ae-9f10-5aa8afa2309f' User entered 'No (N)'	System	10 Nov 2020 20:46:11
	System	10 Nov 2020 20:46:11

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-10T15:46:05', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bc1c022b-67f0-41ae-9f10-5aa8afa2309f' User entered '10 Nov 2020 15:46:05'	System	10 Nov 2020 20:46:11
	System	10 Nov 2020 20:46:11

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:11:56
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06
Data entry locked.	System	06 Aug 2020 14:10:16
User entered 'Day 106'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 14:10:16

US3182192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:17:06
Data entry locked.	System	06 Aug 2020 14:10:16
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 14:10:16

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-22T18:02:49', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '0bf202b2-94f3-4a03-afaa-ed187a6a5e40'	System	22 Nov 2020 23:03:03
User entered 'No (N)'	System	22 Nov 2020 23:03:03

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-22T18:02:54', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '0bf202b2-94f3-4a03-afaa-ed187a6a5e40'	System	22 Nov 2020 23:03:03
User entered 'No (N)'	System	22 Nov 2020 23:03:03

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-22T18:03:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '0bf202b2-94f3-4a03-afaa-ed187a6a5e40'	System	22 Nov 2020 23:03:03
User entered '22 Nov 2020 18:03:00'	System	22 Nov 2020 23:03:03

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 14:52:50
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:40:43
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:41:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-28T08:48:30', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ca7262df-2ba0-447e-9940-6d1813e25e22'	System	28 Nov 2020 13:49:53
User entered 'Yes (Y)'	System	28 Nov 2020 13:49:53

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-28T08:48:37', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ca7262df-2ba0-447e-9940-6d1813e25e22'	System	28 Nov 2020 13:49:53
User entered 'No (N)'	System	28 Nov 2020 13:49:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-28T08:49:14', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ca7262df-2ba0-447e-9940-6d1813e25e22'	System	28 Nov 2020 13:49:53
User entered 'No (N)'	System	28 Nov 2020 13:49:53

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-28T08:49:23', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ca7262df-2ba0-447e-9940-6d1813e25e22'	System	28 Nov 2020 13:49:53
User entered 'Yes (Y)'	System	28 Nov 2020 13:49:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-28T08:49:40', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ca7262df-2ba0-447e-9940-6d1813e25e22'	System	28 Nov 2020 13:49:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Nov 2020 13:49:53

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-11-28T08:49:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ca7262df-2ba0-447e-9940-6d1813e25e22' User entered '28 Nov 2020 08:49:44'	System	28 Nov 2020 13:49:53
	System	28 Nov 2020 13:49:53

US3182192

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:17:06

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 14:52:57
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:40:55
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:42:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-05T07:57:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41747066-0857-413b-bdbc-52e8a8ac6846'	System	05 Dec 2020 12:58:55
User entered 'Yes (Y)'	System	05 Dec 2020 12:58:55

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-05T07:57:58', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41747066-0857-413b-bdbc-52e8a8ac6846'	System	05 Dec 2020 12:58:55
User entered 'No (N)'	System	05 Dec 2020 12:58:55

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-05T07:58:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41747066-0857-413b-bdbc-52e8a8ac6846'	System	05 Dec 2020 12:58:55
User entered 'No (N)'	System	05 Dec 2020 12:58:55

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:35:05

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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-05T07:58:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41747066-0857-413b-bdbc-52e8a8ac6846'	System	05 Dec 2020 12:58:55
User entered 'Yes (Y)'	System	05 Dec 2020 12:58:55

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Folder: New Safety Follow Up Diary (1)

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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.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-05T07:58:39', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41747066-0857-413b-bdbc-52e8a8ac6846'	System	05 Dec 2020 12:58:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 12:58:55

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-05T07:58:45', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '41747066-0857-413b-bdbc-52e8a8ac6846'	System	05 Dec 2020 12:58:55
User entered '05 Dec 2020 07:58:45'	System	05 Dec 2020 12:58:55

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:17:06

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-12T08:33:25', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6d8abbad-7b1d-4b85-a99c-6c0d1225297d'	System	12 Dec 2020 13:33:48
User entered 'No (N)'	System	12 Dec 2020 13:33:48

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-12T08:33:37', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6d8abbad-7b1d-4b85-a99c-6c0d1225297d'	System	12 Dec 2020 13:33:48
User entered 'No (N)'	System	12 Dec 2020 13:33:48

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-12T08:33:44', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '6d8abbad-7b1d-4b85-a99c-6c0d1225297d'	System	12 Dec 2020 13:33:48
User entered '12 Dec 2020 08:33:44'	System	12 Dec 2020 13:33:48

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:17:06

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-21T11:10:48', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'fd1fc671-06d2-4ae1-9cae-95da3502a500'	System	21 Dec 2020 16:11:05
User entered 'No (N)'	System	21 Dec 2020 16:11:05

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-21T11:10:56', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'fd1fc671-06d2-4ae1-9cae-95da3502a500'	System	21 Dec 2020 16:11:05
User entered 'No (N)'	System	21 Dec 2020 16:11:05

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-21T11:11:01', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'fd1fc671-06d2-4ae1-9cae-95da3502a500'	System	21 Dec 2020 16:11:05
User entered '21 Dec 2020 11:11:01'	System	21 Dec 2020 16:11:05

US3182192

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-26T01:05:56', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'dc0a82a7-6f9f-4f9a-b868-3e2df63ebc94'	System	26 Dec 2020 06:06:22
User entered 'No (N)'	System	26 Dec 2020 06:06:22

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-26T01:06:05', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'dc0a82a7-6f9f-4f9a-b868-3e2df63ebc94'	System	26 Dec 2020 06:06:22
User entered 'No (N)'	System	26 Dec 2020 06:06:22

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2020-12-26T01:06:18', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'dc0a82a7-6f9f-4f9a-b868-3e2df63ebc94'	System	26 Dec 2020 06:06:22
User entered '26 Dec 2020 01:06:18'	System	26 Dec 2020 06:06:22

US3182192

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:17:06

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-02T03:52:34', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '0e5f20ca-df36-4dd7-81a4-65d75e4a6388'	System	02 Jan 2021 08:52:50
User entered 'No (N)'	System	02 Jan 2021 08:52:50

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-02T03:52:42', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '0e5f20ca-df36-4dd7-81a4-65d75e4a6388'	System	02 Jan 2021 08:52:50
User entered 'No (N)'	System	02 Jan 2021 08:52:50

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-02T03:52:46', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '0e5f20ca-df36-4dd7-81a4-65d75e4a6388' User entered '02 Jan 2021 03:52:46'	System	02 Jan 2021 08:52:50
	System	02 Jan 2021 08:52:50

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-09T07:03:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7fe540ff-feca-4eab-9636-7fccd45aa8f2'	System	09 Jan 2021 12:03:36
User entered 'No (N)'	System	09 Jan 2021 12:03:36

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-09T07:03:25', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7fe540ff-feca-4eab-9636-7fccd45aa8f2'	System	09 Jan 2021 12:03:36
User entered 'No (N)'	System	09 Jan 2021 12:03:36

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-09T07:03:29', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7fe540ff-feca-4eab-9636-7fccd45aa8f2'	System	09 Jan 2021 12:03:36
User entered '09 Jan 2021 07:03:29'	System	09 Jan 2021 12:03:36

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-18T12:00:47', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '380ad0a5-63fb-49bf-9a58-39d48339f58b' User entered 'No (N)'	System	18 Jan 2021 17:01:43
	System	18 Jan 2021 17:01:43

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-18T12:00:52', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '380ad0a5-63fb-49bf-9a58-39d48339f58b'	System	18 Jan 2021 17:01:43
User entered 'No (N)'	System	18 Jan 2021 17:01:43

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-18T12:00:57', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '380ad0a5-63fb-49bf-9a58-39d48339f58b' User entered '18 Jan 2021 12:00:57'	System	18 Jan 2021 17:01:43
	System	18 Jan 2021 17:01:43

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-23T19:34:23', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8d61fabb-c091-4619-ba0e-154afb4ff187'	System	24 Jan 2021 00:34:40
User entered 'No (N)'	System	24 Jan 2021 00:34:40

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-23T19:34:33', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8d61fabb-c091-4619-ba0e-154afb4ff187'	System	24 Jan 2021 00:34:40
User entered 'No (N)'	System	24 Jan 2021 00:34:40

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-23T19:34:37', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '8d61fabb-c091-4619-ba0e-154afb4ff187'	System	24 Jan 2021 00:34:40
User entered '23 Jan 2021 19:34:37'	System	24 Jan 2021 00:34:40

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-30T16:49:12', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ebd1929e-e6f4-45c2-931e-68c9c5d1e553'	System	30 Jan 2021 21:49:21
User entered 'No (N)'	System	30 Jan 2021 21:49:21

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-30T16:49:15', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ebd1929e-e6f4-45c2-931e-68c9c5d1e553'	System	30 Jan 2021 21:49:21
User entered 'No (N)'	System	30 Jan 2021 21:49:21

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-01-30T16:49:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'ebd1929e-e6f4-45c2-931e-68c9c5d1e553'	System	30 Jan 2021 21:49:21
User entered '30 Jan 2021 16:49:19'	System	30 Jan 2021 21:49:21

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-07T10:31:12', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21dbedb-79d9-4ecd-99ef-335942b4af8a'	System	07 Feb 2021 15:31:26
User entered 'No (N)'	System	07 Feb 2021 15:31:26

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-07T10:31:21', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21dbedb-79d9-4ecd-99ef-335942b4af8a'	System	07 Feb 2021 15:31:26
User entered 'No (N)'	System	07 Feb 2021 15:31:26

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-07T10:31:25', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f21dbedb-79d9-4ecd-99ef-335942b4af8a' User entered '07 Feb 2021 10:31:25'	System	07 Feb 2021 15:31:26
	System	07 Feb 2021 15:31:26

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-15T15:29:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bb0537d1-5355-40c4-a0aa-b3aaebf5de41'	System	15 Feb 2021 20:29:32
User entered 'No (N)'	System	15 Feb 2021 20:29:32

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-15T15:29:26', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bb0537d1-5355-40c4-a0aa-b3aaebf5de41'	System	15 Feb 2021 20:29:32
User entered 'No (N)'	System	15 Feb 2021 20:29:32

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-15T15:29:30', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'bb0537d1-5355-40c4-a0aa-b3aaebf5de41'	System	15 Feb 2021 20:29:32
User entered '15 Feb 2021 15:29:30'	System	15 Feb 2021 20:29:32

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-23T17:59:52', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cebd7123-822b-4613-9bb2-9de7e7a42f4d' User entered 'No (N)'	System	23 Feb 2021 23:00:09
	System	23 Feb 2021 23:00:09

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-23T17:59:59', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cebd7123-822b-4613-9bb2-9de7e7a42f4d' User entered 'No (N)'	System	23 Feb 2021 23:00:09
	System	23 Feb 2021 23:00:09

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-23T18:00:03', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'cebd7123-822b-4613-9bb2-9de7e7a42f4d' User entered '23 Feb 2021 18:00:03'	System	23 Feb 2021 23:00:09
	System	23 Feb 2021 23:00:09

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-28T21:17:12', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '69ef9302-0ba2-4403-bbbf-b30e74b7c46b' User entered 'No (N)'	System	01 Mar 2021 02:27:55
	System	01 Mar 2021 02:27:55

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-28T21:17:16', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '69ef9302-0ba2-4403-bbbf-b30e74b7c46b'	System	01 Mar 2021 02:27:55
User entered 'No (N)'	System	01 Mar 2021 02:27:55

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-28T21:17:19', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '69ef9302-0ba2-4403-bbbf-b30e74b7c46b' User entered '28 Feb 2021 21:17:19'	System	01 Mar 2021 02:27:55
	System	01 Mar 2021 02:27:55

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-06T04:14:32', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7c480239-3270-472e-8af4-fb3bb080720f' User entered 'No (N)'	System	06 Mar 2021 09:14:48
	System	06 Mar 2021 09:14:48

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-06T04:14:41', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7c480239-3270-472e-8af4-fb3bb080720f' User entered 'No (N)'	System	06 Mar 2021 09:14:48
	System	06 Mar 2021 09:14:48

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-06T04:14:46', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '7c480239-3270-472e-8af4-fb3bb080720f' User entered '06 Mar 2021 04:14:46'	System	06 Mar 2021 09:14:48

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-13T19:37:48', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c058717-46e7-49bd-b3e5-aad3357a6075'	System	14 Mar 2021 00:38:07
User entered 'No (N)'	System	14 Mar 2021 00:38:07

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-13T19:37:58', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c058717-46e7-49bd-b3e5-aad3357a6075'	System	14 Mar 2021 00:38:07
User entered 'No (N)'	System	14 Mar 2021 00:38:07

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-13T19:38:04', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1c058717-46e7-49bd-b3e5-aad3357a6075'	System	14 Mar 2021 00:38:07
User entered '13 Mar 2021 19:38:04'	System	14 Mar 2021 00:38:07

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-21T11:57:41-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'fb02ab23-f08a-4578-8aed-34d29d7ab11d'	System	21 Mar 2021 15:57:54
User entered 'No (N)'	System	21 Mar 2021 15:57:54

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-21T11:57:48-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'fb02ab23-f08a-4578-8aed-34d29d7ab11d'	System	21 Mar 2021 15:57:54
User entered 'No (N)'	System	21 Mar 2021 15:57:54

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-21T11:57:51-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'fb02ab23-f08a-4578-8aed-34d29d7ab11d' User entered '21 Mar 2021 11:57:51'	System	21 Mar 2021 15:57:54
	System	21 Mar 2021 15:57:54

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-27T00:02:36-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f5202022-6207-4dd3-a84b-985ac286b52b'	System	27 Mar 2021 04:08:13
User entered 'No (N)'	System	27 Mar 2021 04:08:13

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-27T00:02:43-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f5202022-6207-4dd3-a84b-985ac286b52b'	System	27 Mar 2021 04:08:13
User entered 'No (N)'	System	27 Mar 2021 04:08:13

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-03-27T00:02:48-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'f5202022-6207-4dd3-a84b-985ac286b52b' User entered '27 Mar 2021 00:02:48'	System	27 Mar 2021 04:08:13
	System	27 Mar 2021 04:08:13

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-05T14:53:32-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '363e124a-f4d3-40e1-ba56-c8e638d6c497'	System	05 Apr 2021 18:54:24
User entered 'Yes (Y)'	System	05 Apr 2021 18:54:24

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-05T14:53:38-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '363e124a-f4d3-40e1-ba56-c8e638d6c497' User entered 'No (N)'	System	05 Apr 2021 18:54:24
	System	05 Apr 2021 18:54:24

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-05T14:53:44-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '363e124a-f4d3-40e1-ba56-c8e638d6c497'	System	05 Apr 2021 18:54:24
User entered 'No (N)'	System	05 Apr 2021 18:54:24

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-05T14:53:54-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '363e124a-f4d3-40e1-ba56-c8e638d6c497'	System	05 Apr 2021 18:54:24
User entered 'Yes (Y)'	System	05 Apr 2021 18:54:24

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-05T14:54:09-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '363e124a-f4d3-40e1-ba56-c8e638d6c497'	System	05 Apr 2021 18:54:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 18:54:24

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-05T14:54:12-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '363e124a-f4d3-40e1-ba56-c8e638d6c497'	System	05 Apr 2021 18:54:24
User entered '05 Apr 2021 14:54:12'	System	05 Apr 2021 18:54:24

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-12T12:08:53-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c72beadf-5277-4af1-a624-045af162029c'	System	12 Apr 2021 16:15:06
User entered 'Yes (Y)'	System	12 Apr 2021 16:15:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-12T12:08:58-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c72beadf-5277-4af1-a624-045af162029c'	System	12 Apr 2021 16:15:06
User entered 'No (N)'	System	12 Apr 2021 16:15:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-12T12:09:04-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c72beadf-5277-4af1-a624-045af162029c'	System	12 Apr 2021 16:15:06
User entered 'No (N)'	System	12 Apr 2021 16:15:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-12T12:09:23-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c72beadf-5277-4af1-a624-045af162029c'	System	12 Apr 2021 16:15:06
User entered 'Yes (Y)'	System	12 Apr 2021 16:15:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-12T12:09:29-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c72beadf-5277-4af1-a624-045af162029c'	System	12 Apr 2021 16:15:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Apr 2021 16:15:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-12T12:09:34-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c72beadf-5277-4af1-a624-045af162029c'	System	12 Apr 2021 16:15:06
User entered '12 Apr 2021 12:09:34'	System	12 Apr 2021 16:15:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-19T12:00:43-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '58360594-72c0-4590-ac07-4532b24eac81'	System	19 Apr 2021 16:06:42
User entered 'Yes (Y)'	System	19 Apr 2021 16:06:42

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-19T12:00:49-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '58360594-72c0-4590-ac07-4532b24eac81'	System	19 Apr 2021 16:06:42
User entered 'No (N)'	System	19 Apr 2021 16:06:42

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-19T12:00:56-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '58360594-72c0-4590-ac07-4532b24eac81'	System	19 Apr 2021 16:06:42
User entered 'No (N)'	System	19 Apr 2021 16:06:42

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-19T12:01:06-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '58360594-72c0-4590-ac07-4532b24eac81'	System	19 Apr 2021 16:06:42
User entered 'Yes (Y)'	System	19 Apr 2021 16:06:42

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Please 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-19T12:01:12-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '58360594-72c0-4590-ac07-4532b24eac81'	System	19 Apr 2021 16:06:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 16:06:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-19T12:01:16-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '58360594-72c0-4590-ac07-4532b24eac81'	System	19 Apr 2021 16:06:42
User entered '19 Apr 2021 12:01:16'	System	19 Apr 2021 16:06:42

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-26T12:01:48-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '76203052-58c8-451c-bd2c-652298320751'	System	26 Apr 2021 16:06:53
User entered 'No (N)'	System	26 Apr 2021 16:06:53

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-26T12:01:53-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '76203052-58c8-451c-bd2c-652298320751'	System	26 Apr 2021 16:06:53
User entered 'No (N)'	System	26 Apr 2021 16:06:53

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-04-26T12:01:58-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '76203052-58c8-451c-bd2c-652298320751'	System	26 Apr 2021 16:06:53
User entered '26 Apr 2021 12:01:58'	System	26 Apr 2021 16:06:53

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-05-01T12:11:54-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c6a4a0ae-4a1a-4116-a42a-cc365c3335e4'	System	01 May 2021 16:12:57
User entered 'No (N)'	System	01 May 2021 16:12:57

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

Have you been exposed to someone with 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 (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-05-01T12:11:58-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c6a4a0ae-4a1a-4116-a42a-cc365c3335e4'	System	01 May 2021 16:12:57
User entered 'No (N)'	System	01 May 2021 16:12:57

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-05-01T12:12:03-04:00', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: 'c6a4a0ae-4a1a-4116-a42a-cc365c3335e4'	System	01 May 2021 16:12:57
User entered '01 May 2021 12:12:03'	System	01 May 2021 16:12:57

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:17:06

US3182192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:35:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:17:06
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:17:06

US3182192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:35:05

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 12:54:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-28T21:17:30', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1cabf349-859a-450e-8a1a-faef1a244773'	System	01 Mar 2021 02:28:14
User entered 'No (N)'	System	01 Mar 2021 02:28:14

US3182192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:35:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:54:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1206644F-BEAB-4C95-9742-95587FEF3478)', Time: '2021-02-28T21:17:38', User OID: 'PatientReportedOutcome (US3182192)', ODM File OID: '1cabf349-859a-450e-8a1a-faef1a244773' User entered '28 Feb 2021 21:17:38'	System	01 Mar 2021 02:28:14
	System	01 Mar 2021 02:28:14

US3182192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:24:03

US3182192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '29 Oct 2020'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:24:03

US3182192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:24:03

US3182192

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:24:03
	(b) (4)	

US3182192

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:24:19

US3182192

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:06:12
User entered 'I'	System	13 Nov 2020 16:24:19

US3182192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Dec 2020 03:06:41

US3182192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '01 Dec 2020'	(b) (4) Cassie Uminski (b) (4)	10 Dec 2020 03:06:41

US3182192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4)	10 Dec 2020 03:06:41

US3182192

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	10 Dec 2020 03:06:41
	(b) (4)	

US3182192

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	10 Dec 2020 03:06:30

US3182192

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered 'I'	System	10 Dec 2020 03:06:30

US3182192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Gabby Jacobs (b) (4) (b) (4)	31 Dec 2020 17:44:26

US3182192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 28JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 09:31:23
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 28JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Please note that there is already the same query listed under the day 179 call' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	19 Feb 2021 16:04:12
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 28JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:13:45
User entered '31 Dec 2020'	Gabby Jacobs (b) (4) (b) (4)	31 Dec 2020 17:44:26

US3182192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Contact Made (CONTACT MADE)'	Gabby Jacobs (b) (4)	31 Dec 2020 17:44:26

US3182192

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Gabby Jacobs (b) (4) (b) (4)	31 Dec 2020 17:44:26

US3182192

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Gabby Jacobs (b) (4)	31 Dec 2020 17:45:09

US3182192

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered '1'	System	31 Dec 2020 17:45:09

US3182192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 28JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 21:13:01
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 28JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:37
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 28JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:39:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Feb 2021 14:36:09

US3182192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	04 Feb 2021 14:36:09

US3182192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4)	04 Feb 2021 14:36:09

US3182192

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	04 Feb 2021 14:36:09

US3182192

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	04 Feb 2021 14:36:00

US3182192

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered '1'	System	04 Feb 2021 14:36:00

US3182192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 18:56:22

US3182192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:56:22

US3182192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	01 Mar 2021 18:56:22

US3182192

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered 'VISIT4'	System	01 Mar 2021 18:56:22

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered '09:07'	Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered '23 Feb 2021 09:07'	System	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered '97.9' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered '66'	Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered 'bpm'	System	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered '16'	Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered 'breaths/min'	System	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered '127'	Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered 'mmHg'	System	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:54:41
User entered '81'	Cassie Uminski (b) (4)	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered 'mmHg'	System	31 Mar 2021 12:57:43

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25

US3182192

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25

US3182192

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 18:56:31

US3182192

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:56:31

US3182192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 18:57:37

US3182192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:57:37

US3182192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '14:49'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:57:37

US3182192

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered '23 Feb 2021 14:49'	System	01 Mar 2021 18:57:37

US3182192

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 18:57:42

US3182192

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:34:25
User entered '1'	System	01 Mar 2021 18:57:42

US3182192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:48:40
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 15:03:17

US3182192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:48:40
User entered '30 Mar 2021'	(b) (4) Cassie Uminski (b) (4)	07 Apr 2021 15:03:17
	(b) (4)	

US3182192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:48:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	07 Apr 2021 15:03:17

US3182192

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:48:40
User entered empty.	(b) (4) Cassie Uminski (b) (4)	07 Apr 2021 15:03:17
	(b) (4)	

US3182192

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:54
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:48:40
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	07 Apr 2021 15:03:21

US3182192

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:40:54
User entered '1'	System	07 Apr 2021 15:03:21

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:56:25

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:56:25

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	01 Mar 2021 13:56:25

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'UNBLND_DECIDE'	System	01 Mar 2021 13:56:25

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Toby Briskin (b) (4)	10 Apr 2021 21:24:36
User entered '0'	(b) (4) Naqib Ahmad (b) (4)	09 Apr 2021 19:28:43
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 16:20:13

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4)	14 Apr 2021 13:07:23
	Toby Briskin (b) (4)	10 Apr 2021 21:24:36
	(b) (4)	
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Naqib Ahmad (b) (4)	09 Apr 2021 19:28:58
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Naqib Ahmad (b) (4)	09 Apr 2021 19:28:43
	(b) (4)	
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	09 Apr 2021 16:52:58
	System	06 Mar 2021 16:20:13

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Placebo (Placebo)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Placebo (Placebo)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Placebo (Placebo)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '1'	System	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:35:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '1'	System	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '165.4' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '78.3' kg	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28.62139'	System	01 Mar 2021 13:59:14
DataPoint set to visible.	System	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '165.4' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '78.3' kg	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28.62139'	System	01 Mar 2021 13:59:14
DataPoint set to visible.	System	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '14:50'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28 Jan 2021 14:50'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '98.1' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '58'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'bpm'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '16'	Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'breaths/min'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '117'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '75'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '165.4' cm	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '78.3' kg	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:35:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28.62139'	System	01 Mar 2021 13:59:14
DataPoint set to visible.	System	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '15:50'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28 Jan 2021 15:50'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '98.4' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '63'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'bpm'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'breaths/min'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '121'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '74'	Cassie Uminski (b) (4)	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	01 Mar 2021 13:59:14

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:28

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:59:28

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:58:03
	(b) (4)	

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mRNA-1273'	System	01 Mar 2021 13:58:03
DataPoint set to visible.	System	01 Mar 2021 13:57:27

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '15:20'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28 Jan 2021 15:20'	System	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'ONCE'	System	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 13:58:03

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:57:05

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:05

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '15:50'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:57:05

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28 Jan 2021 15:50'	System	01 Mar 2021 13:57:05

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:56:35

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '28 Jan 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:56:35

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '14:50'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:56:35

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:35:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '28 Jan 2021 14:50'	System	01 Mar 2021 13:56:35

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:57:46

US3182192

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '1'	System	01 Mar 2021 13:57:46

US3182192

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 14:01:30

US3182192

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '04 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 14:01:30

US3182192

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 14:01:30

US3182192

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 14:01:30

US3182192

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 14:01:36

US3182192

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '1'	System	01 Mar 2021 14:01:36

US3182192

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '1'	System	01 Mar 2021 14:01:36
DataPoint set to visible.	System	01 Mar 2021 14:01:36

US3182192

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	02 Mar 2021 18:20:30

US3182192

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:20:30

US3182192

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	02 Mar 2021 18:20:30

US3182192

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'OLD29'	System	02 Mar 2021 18:20:30

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	04 Mar 2021 15:15:33
User entered '09:07' reason for change: Data Entry Error	Cassie Uminski (b) (4)	04 Mar 2021 15:15:33
	(b) (4)	
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	02 Mar 2021 18:22:25
User entered '10:17'	Cassie Uminski (b) (4)	02 Mar 2021 18:21:38
	(b) (4)	

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '23 Feb 2021 09:07'	System	04 Mar 2021 15:15:33
User entered '23 Feb 2021 10:17'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '97.9' F	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '66'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'bpm'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'breaths/min'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '127'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '81'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:35:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '10:17'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '23 Feb 2021 10:17'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '98.1' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '72'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'bpm'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'breaths/min'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '138'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '80'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	02 Mar 2021 18:21:38

US3182192

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:21:48

US3182192

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:21:48

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mRNA-1273'	System	02 Mar 2021 18:22:25
DataPoint set to visible.	System	01 Mar 2021 14:01:36

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '23 Feb 2021'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '09:47'	(b) (4) Cassie Uminski (b) (4)	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '23 Feb 2021 09:47'	System	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'ONCE'	System	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:35:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 18:22:25

US3182192

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	02 Mar 2021 18:22:05

US3182192

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '1'	System	02 Mar 2021 18:22:05

US3182192

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:03:24
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	15 Mar 2021 18:56:27

US3182192

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:03:24
User entered '05 Mar 2021'	(b) (4) Cassie Uminski (b) (4)	15 Mar 2021 18:56:27

US3182192

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:03:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4)	15 Mar 2021 18:56:27

US3182192

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:35:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:03:24
User entered empty.	(b) (4) Cassie Uminski (b) (4)	15 Mar 2021 18:56:27

US3182192

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:03:24
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	15 Mar 2021 18:56:36

US3182192

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:35:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'I'	System	15 Mar 2021 18:56:36

US3182192

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:23

US3182192

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '22 Mar 2021'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:23

US3182192

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:23

US3182192

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:35:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'OLD57'	System	22 Mar 2021 19:43:23

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '22 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '09:05'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '22 Mar 2021 09:05'	System	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '97.8' F	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered empty.	(b) (4) Cassie Uminski (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '80'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'bpm'	System	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'breaths/min'	System	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '120'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '78'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered 'mmHg'	System	22 Mar 2021 19:43:40

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41

US3182192

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:35:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41

US3182192

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:48

US3182192

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:35:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '22 Mar 2021'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:48

US3182192

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	22 Mar 2021 19:43:58

US3182192

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '22 Mar 2021'	(b) (4) Cassie Uminski (b) (4)	22 Mar 2021 19:43:58

US3182192

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:43:36
User entered '09:15'	(b) (4) Cassie Uminski (b) (4) (b) (4)	22 Mar 2021 19:43:58

US3182192

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:35:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:02:41
User entered '22 Mar 2021 09:15'	System	22 Mar 2021 19:43:58

US3182192

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:35:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:25
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:44:35

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:44:43
DataPoint Verified.		08 Dec 2020 17:15:54
User entered 'USA-US075-2020-mRNA-1273-P301000005'	System	30 Nov 2020 17:08:46
User entered 'New'	(b) (4), (b) (6)	30 Nov 2020 17:08:46

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:28:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	07 Apr 2021 11:28:18 29 Mar 2021 18:46:16
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:10
Data point term sent to Coder DataPoint Un-verified.	System Cassie Uminski (b) (4)	25 Mar 2021 15:41:18 25 Mar 2021 15:40:51
Coding entries removed.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:40:51
Signature has been broken.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:40:51
User entered 'SEVERE EPISTAXIS SECONDARY TO NASAL SURGICAL COMPLICATION' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:40:51
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:12:02
User closed query 'For coding purposes, please split SEVERE EPISTAXIS/ANEMIA SECONDARY TO NASAL SURGICAL COMPLICATION into separate entries. 1. SEVERE EPISTAXIS [SECONDARY TO NASAL SURGICAL COMPLICATION] and 2. ANEMIA SECONDARY TO NASAL SURGICAL COMPLICATION ' (Site from Coder).		28 Jan 2021 18:01:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:09:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:09:08
Data point term sent to Coder	System	08 Jan 2021 15:35:20

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
Query 'For coding purposes, please split SEVERE EPISTAXIS/ANEMIA SECONDARY TO NASAL SURGICAL COMPLICATION into separate entries. 1.SEVERE EPISTAXIS [SECONDARY TO NASAL SURGICAL COMPLICATION] and 2. ANEMIA SECONDARY TO NASAL SURGICAL COMPLICATION ' answered with 'Updated' (Site from Coder). DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:34:37
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:34:30
User entered 'SEVERE EPISTAXIS SECONDARY TO NASAL SURGICAL COMPLICATION' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:34:30
User opened query 'For coding purposes, please split SEVERE EPISTAXIS/ANEMIA SECONDARY TO NASAL SURGICAL COMPLICATION into separate entries. 1.SEVERE EPISTAXIS [SECONDARY TO NASAL SURGICAL COMPLICATION] and 2. ANEMIA SECONDARY TO NASAL SURGICAL COMPLICATION ' (Site from Coder).	(b) (4), (b) (6)	26 Dec 2020 16:48:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural haemorrhage, LLT: Postoperative bleeding - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Dec 2020 13:49:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Dec 2020 13:49:45
Query 'PV Query: The event term severe epistaxis/anemia secondary to nasal surgical complication contains multiple event terms. Please consider separating them into separate events.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:03:05
User opened query 'PV Query: The event term severe epistaxis/anemia secondary to nasal surgical complication contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:00:25

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
Data point term sent to Coder	System	03 Dec 2020 16:00:25
Coding entries removed.	Cassie Uminski (b) (4)	03 Dec 2020 15:59:56
	(b) (4)	
User entered 'SEVERE EPISTAXIS/Anemia SECONDARY TO NASAL SURGical complication'	Cassie Uminski (b) (4)	03 Dec 2020 15:59:56
reason for change: Data Entry Error	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\23.0.	Coder Import (b) (4)	26 Nov 2020 08:30:06
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Nov 2020 08:30:06
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 17:08:43
User entered 'Severe Epistaxis secondary to nasal surgery' reason for change: Data Entry Error	Cassie Uminski (b) (4)	25 Nov 2020 17:08:19
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 16:55:32
User entered 'Severe blood loss'	Cassie Uminski (b) (4)	25 Nov 2020 16:54:47
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'PV Query: Please confirm event start date as first episode of epistaxis occurred on 20 Nov 2020. Please update start date to date of onset of symptoms.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 21:03:12
User opened query 'PV Query: Please confirm event start date as first episode of epistaxis occurred on 20 Nov 2020. Please update start date to date of onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:59:48
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '22 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:12:09
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).		02 Mar 2021 15:18:04
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'Updated form to reflect most current data' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:41:17
DataPoint Un-verified.	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:40:49
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:40:49
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:05:50
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	28 Apr 2021 09:14:06
DataPoint Verified.	(b) (4)	26 Apr 2021 19:14:52
User closed query 'Please clarify if the epistaxis lasted until 26Nov. From the records it looks like it stopped no later than 23Nov. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 19:14:39
Query 'Please clarify if the epistaxis lasted until 26Nov. From the records it looks like it stopped no later than 23Nov. ' answered with 'Updated and confirmed per records ' (Site from CRA).	Jennifer Gaston (b) (4)	26 Apr 2021 16:59:02
Signature has been broken.	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:58:35
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Gaston (b) (4)	26 Apr 2021 16:58:35
User opened query 'Please clarify if the epistaxis lasted until 26Nov. From the records it looks like it stopped no later than 23Nov. ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 16:50:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4)	02 Mar 2021 19:12:18
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:37:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated data' (Site from Safety).	Jennifer Gaston (b) (4)	28 Feb 2021 21:41:31
DataPoint Un-verified.	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 21:40:49
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Gaston (b) (4)	28 Feb 2021 21:40:49
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:06:12
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 21:00:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Records have been requested' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:35:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:30:30
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.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:03:14
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:59:13
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Grade 4 (Grade 4)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '0'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '0'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		04 Dec 2020 03:41:09
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still in patient at hospital, information will be updated once available.' (Site from System).	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:56:47
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	25 Nov 2020 16:54:47
User entered '1'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '23 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 14:30:02
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '26 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4)	03 Dec 2020 15:59:56
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '0'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '0'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '0'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:51:42
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:43:07
User closed query 'Per DM CLR - RQ: Site's response noted. However, if verified that Concomitant Medication #19 was used for this AE; then it should be reflected as such in the AE eCRF. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 22:42:07
Query 'Per DM CLR - RQ: Site's response noted. However, if verified that Concomitant Medication #19 was used for this AE; then it should be reflected as such in the AE eCRF. Please review and update AE eCRF as appropriate. ' answered with 'confirmed and updated' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 13:22:20
DataPoint Un-verified.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 13:22:02
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 13:22:02
User entered '0' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	07 Apr 2021 13:22:02
User opened query 'Per DM CLR - RQ: Site's response noted. However, if verified that Concomitant Medication #19 was used for this AE; then it should be reflected as such in the AE eCRF. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:27:17
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:18:01
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #19 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:09:32

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

None

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #19 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'Correct as is per investigator' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:41:00
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #19 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:55:31
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
DataPoint Un-verified.	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:16:16
User entered '1' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:16:16
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '0'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:51:44
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:43:07
DataPoint Un-verified.	Jennifer Gaston (b) (4)	07 Apr 2021 13:22:02
Signature has been broken.	Jennifer Gaston (b) (4)	07 Apr 2021 13:22:02
User entered '1' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	07 Apr 2021 13:22:02
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '0'	Cassie Uminski (b) (4)	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:17:55
User closed query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:37:42
Query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'confirmed- records to be sent' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 16:55:06
User opened query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:28:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send CT scan, chest xray, and scope of airway when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' Revised 11 Mar 2021 PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.'	(b) (4), (b) (6)	12 Mar 2021 17:25:01
canceled (Site from Safety). User opened query 'PV Query: Please send CT scan, chest xray, and scope of airway when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.'	(b) (4), (b) (6)	12 Mar 2021 17:24:52
Revised 11 Mar 2021 PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User closed query 'Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:08
Query 'Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' answered with 'updated per medical records' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:16:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Gaston (b) (4)	01 Mar 2021 00:16:16
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Jennifer Gaston (b) (4)	01 Mar 2021 00:16:16
User opened query 'Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 16:10:49
User closed query 'Per DM CLR: Other Action Take = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		21 Jan 2021 16:10:49
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Records have been requested' (Site from DM).	Cassie Uminski (b) (4)	08 Jan 2021 15:35:22
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:23:52
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered '1'	Cassie Uminski (b) (4)	25 Nov 2020 16:54:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Please clarify as source has recovered with sequelae' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:16:17
DataPoint Verified.		30 Mar 2021 19:16:14
Query 'Please clarify as source has recovered with sequelae' answered with 'Was entered in error by Inv. this was confirmed ' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	26 Mar 2021 17:03:52
User opened query 'Please clarify as source has recovered with sequelae' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:37:18
User closed query 'Please clarify as source has recovered with sequelae. ' (Site from CRA).		26 Mar 2021 14:37:18
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	04 Mar 2021 15:24:38
Query 'Please clarify as source has recovered with sequelae. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	04 Mar 2021 15:19:08
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	04 Mar 2021 15:17:19
User opened query 'Please clarify as source has recovered with sequelae. ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 19:14:01
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		01 Mar 2021 15:38:00
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated as event has resolved' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:43:32
DataPoint Un-verified.	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	28 Feb 2021 21:40:49
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:05:50
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 21:00:12
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Records have been requested' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:35:28
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:30:18
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:03:20
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:59:03
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	04 Mar 2021 15:24:38
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	04 Mar 2021 15:17:19
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 17:15:48
User entered empty.	Cassie Uminski (b) (4)	25 Nov 2020 16:54:47
	(b) (4)	

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Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:17:47
User closed query 'Per DM CLR: Narrative = LABS DRAWN. 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 Mar 2021 08:13:46
User closed query 'Per DM CLR: Narrative = CHEST TIGHTNESS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:13:37
User closed query 'Per DM CLR: Narrative = SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK. 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 Mar 2021 08:13:29
User closed query 'Per DM CLR: Narrative = SEVERE NOSE BLEEDS ON 11/20/20. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:12:47
Query 'Per DM CLR: Narrative = CHEST TIGHTNESS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'AE updated' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:11:56
Query 'Per DM CLR: Narrative = SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'con proc updated' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:10:07
Query 'Per DM CLR: Narrative = LABS DRAWN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:44:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SEVERE NOSE BLEEDS ON 11/20/20. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:42:45
User opened query 'Per DM CLR: Narrative = LABS DRAWN. 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)	13 Mar 2021 01:56:18
User opened query 'Per DM CLR: Narrative = CHEST TIGHTNESS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:55:55
User opened query 'Per DM CLR: Narrative = SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK. 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)	13 Mar 2021 01:55:48
User opened query 'Per DM CLR: Narrative = SEVERE NOSE BLEEDS ON 11/20/20. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:55:42
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User closed query ' Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:14
User closed query ' Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:18:12
User closed query 'Per DM CLR: SAE Narrative = SUBJECT REPORTS SHE HAD SYNCOPAL EPISODE WHILE IN ER. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:38:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:38:12
User closed query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:38:08
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:38:06
Query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:23:22
Query ' Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' answered with 'Pages updated with medical record data' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:43:28
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated appropriate logs to reflect medical record data' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:42:59
DataPoint Un-verified.	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:42:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON NOVEMBER 11 SUBJECT WAS SEEN BY ENT TO HAVE SEPTOPLASTY PERFORMED TO REPAIR DEVIATED SEPTUM. SUBJECT HAD STENTS TAKEN OUT ON 11/18/20. SUBJECT REPORTS 2 SEVERE NOSE BLEEDS ON 11/20/20 AND 11/22/20. SUBJECT CALLED AMBULANCE ON 11/22/20 AROUND 10 P.M. AND WAS TAKEN TO ER. SUBJECT REPORTS SHE HAD SYNCOPAL EPISODE WHILE IN ER AND WAS TRANSFERRED TO METRO HOSPITAL DUE TO BLOOD LOSS. PATIENT REPORTS SHE REMAINS HOSPITALIZED AND WAS SEEN BY ENT SPECIALIST 11/25/20 TO ASSESS BLOOD IN AIRWAY. SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK AWAITING RESULTS. RECORDS WILL BE REQUESTED. Records received. Subject had septoplasty performed on 11/11/2020. On 11/22/2020 subject was taken to the ER by ambulance for nose bleed. Subject stated the nose bled lasted a few minutes in duration. At arrival the subject was very anxious and complained of chest tightness and suffered a brief syncopal episode. The subject confirmed the chest tightness subsided after her syncope subsided. IV fluids given. The subject had an EKG (sinus rhythm, 83BPM, left axis deviation, no ST elevation, nonspecific t wave flattening, no evidence of acute criteria for cath lab. Labs drawn, within normal limits. Treatments given added to appropriate logs' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:42:29
Query ' Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' answered with 'records received, narrative updated and records to be redacted and sent ' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:25:05
Query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' answered with 'Confirmed per medical records, medical history updated' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:24:44

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = SUBJECT REPORTS SHE HAD SYNCOPAL EPISODE WHILE IN ER. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Confirmed, AE log updated' (Site from DM).	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:20:29
User opened query ' Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 16:13:41
User closed query 'Per DM CLR: SAE Narrative = SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK AWAITING RESULTS. However, these were 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)	21 Jan 2021 16:13:41
User opened query ' Per CDM: Thank you for your response, however, Let the query be left opened until the records received.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 16:13:33
User closed query 'Per DM CLR: SAE Narrative = ON NOVEMBER 11 SUBJECT WAS SEEN BY ENT TO HAVE SEPTOPLASTY PERFORMED TO REPAIR DEVIATED SEPTUM. 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)	21 Jan 2021 16:13:33
User opened query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:06:40
User opened query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:06:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:04:56
User closed query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 21:00:39
User closed query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 21:00:31
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 21:00:21
Query 'Per DM CLR: SAE Narrative = SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK AWAITING RESULTS. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Records have been requested' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:36:53
Query 'Per DM CLR: SAE Narrative = ON NOVEMBER 11 SUBJECT WAS SEEN BY ENT TO HAVE SEPTOPLASTY PERFORMED TO REPAIR DEVIATED SEPTUM. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Records have been requested' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:36:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' answered with 'Records have been requested' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:35:49
Query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' answered with 'Records have been requested' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:35:44
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Records have been requested' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	08 Jan 2021 15:35:38
User opened query 'Per DM CLR: SAE Narrative = SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK AWAITING RESULTS. However, these were 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)	08 Jan 2021 06:23:21
User opened query 'Per DM CLR: SAE Narrative = SUBJECT REPORTS SHE HAD SYNCOPAL EPISODE WHILE IN ER. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 06:22:26
User opened query 'Per DM CLR: SAE Narrative = ON NOVEMBER 11 SUBJECT WAS SEEN BY ENT TO HAVE SEPTOPLASTY PERFORMED TO REPAIR DEVIATED SEPTUM. 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)	08 Jan 2021 06:22:14
User opened query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:30:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:30:38
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:30:12
Query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:03:26
Query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:03:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:03:22
User opened query 'PV Query: Please confirm if deviated septum is considered medical history (prior to start of study). If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:59:34
User opened query 'PV query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 20:59:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:58:47
	(b) (4), (b) (6)	08 Dec 2020 17:15:46
User entered 'ON NOVEMBER 11 SUBJECT WAS SEEN BY ENT TO HAVE SEPTOPLASTY PERFORMED TO REPAIR DEVIATED SEPTUM. SUBJECT HAD STENTS TAKEN OUT ON 11/18/20. SUBJECT REPORTS 2 SEVERE NOSE BLEEDS ON 11/20/20 AND 11/22/20. SUBJECT CALLED AMBULANCE ON 11/22/20 AROUND 10 P.M. AND WAS TAKEN TO ER. SUBJECT REPORTS SHE HAD SYNCOPAL EPISODE WHILE IN ER AND WAS TRANSFERRED TO METRO HOSPITAL DUE TO BLOOD LOSS. PATIENT REPORTS SHE REMAINS HOSPITALIZED AND WAS SEEN BY ENT SPECIALIST 11/25/20 TO ASSESS BLOOD IN AIRWAY. SHE HAD CT SCAN WITH CONTRAST AS WELL AS CHEST XRAY, SCOPE OF AIRWAY AND BLOOD WORK AWAITING RESULTS. RECORDS will BE REQUESTED.' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:59:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'On November 11 subject was seen by ENT to have septoplasty performed to repair deviated septum. Subject had stents taken out on 11/18/20. Subject reports 2 severe nose bleeds on 11/20/20 and 11/22/20. Subject called Ambulance on 11/22/20 around 10 p.m. and was taken to ER. Subject reports she had syncopal episode while in ER and was transferred to Metro Hospital due to blood loss. Patient reports she remains hospitalized and was seen by ENT specialist 11/25/20 to assess blood in airway. She had CT scan with contrast as well as chest Xray, scope of airway and blood work awaiting results. Records have been requested.'	Cassie Uminski (b) (4) (b) (4)	25 Nov 2020 16:54:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 16:54:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 16:54:47

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 00:19:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 00:19:37
Data point term sent to Coder	System	01 Mar 2021 00:19:08
User entered 'Syncope'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '22 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User entered empty.	System	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '22 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User entered empty.	System	01 Mar 2021 00:18:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Mar 2021 00:19:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 00:19:24
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	01 Mar 2021 00:19:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Mar 2021 00:18:55
User entered empty.	System	01 Mar 2021 00:18:55
	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Mar 2021 00:19:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 00:19:24
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	01 Mar 2021 00:19:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Mar 2021 00:18:55
User entered empty.	System	01 Mar 2021 00:18:55
	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Mar 2021 00:19:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 00:19:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	01 Mar 2021 00:19:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Mar 2021 00:18:55
User entered empty.	System	01 Mar 2021 00:18:55
	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '1'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

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 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Jennifer Gaston (b) (4)	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User entered '0'	System	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41
User entered '1'	System	01 Mar 2021 00:18:55

US3182192

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:35:05

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:41

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 13:26:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:26:55
Data point term sent to Coder	System	01 Mar 2021 13:26:02
User entered 'Anemia'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '22 Nov 2020'	Cassie Uminski (b) (4)	01 Mar 2021 13:25:42
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:25:42
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	01 Mar 2021 13:25:42
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	01 Mar 2021 13:25:42
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

None

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '1'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cassie Uminski (b) (4)	01 Mar 2021 13:25:42
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:25:42
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:35:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 13:25:42

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:43:07
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:28:56

fb

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 10:16:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Mar 2021 10:16:42
Data point term sent to Coder	System	25 Mar 2021 15:47:29
User entered 'Epistaxis (secondary to nasal surgery)'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '20 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User entered empty.	System	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '20 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User entered empty.	System	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User closed query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 00:33:34
Query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'confirmed sent ' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	13 Apr 2021 21:03:07
User opened query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:28:50
Query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.---Site responded on 25 Mar 2021: "confirmed-records to be sent" canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:28:26

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send CT scan, chest xray, scope of airway and lab work results (including H&H, platelets and coags) when available with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.----Site responded on 25 Mar 2021: "confirmed-records to be sent"' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [Redacted]	02 Apr 2021 15:28:07
User entered empty.	Mary Beth Manning (b) (4) Cassie Uminski (b) (4) [Redacted]	26 Mar 2021 13:19:10 25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '1'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

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 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User entered '0'	System	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45
User entered '0'	System	25 Mar 2021 15:46:31

US3182192

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:45

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:43:07
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 12:18:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 12:18:59
Data point term sent to Coder	System	08 Apr 2021 20:13:22
Coding entries removed.	Jennifer Gaston (b) (4)	08 Apr 2021 20:13:15
Signature has been broken.	Jennifer Gaston (b) (4)	08 Apr 2021 20:13:15
User entered 'CHEST TIGHTNESS-unknown etiology' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	08 Apr 2021 20:13:15
User closed query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	08 Apr 2021 20:12:55
Query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'unknown etiology updated term' (Site from System).	Jennifer Gaston (b) (4)	08 Apr 2021 20:12:55
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:10
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 17:14:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 17:14:34

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	25 Mar 2021 17:13:35
User entered 'Chest Tightness'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '22 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User entered empty.	System	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '22 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User entered empty.	System	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'No (N)'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 17:13:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 17:13:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 17:13:23
User entered empty.	System	25 Mar 2021 17:13:23
	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 17:13:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 17:13:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 17:13:23
User entered empty.	System	25 Mar 2021 17:13:23
	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23
	(b) (4)	

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 17:13:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 17:13:40
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 17:13:23
User entered empty.	System	25 Mar 2021 17:13:23
	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '1'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '0'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

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 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User entered '0'	System	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56
User entered '1'	System	25 Mar 2021 17:13:23

US3182192

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:26:56

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	30 Apr 2021 20:37:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:25:49
User entered 'USA-US075-2020-mRNA-1273-P301000005'		30 Apr 2021 13:25:06

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 08:37:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 08:37:24
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
Data point term sent to Coder	System	29 Apr 2021 17:44:20
User entered 'Hypoxia secondary to Chronic Obstructive pulmonary disease and Asthma'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '24 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '25 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Grade 4 (Grade 4)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User signature succeeded.	(b) (4), (b) (6) Toby Briskin (b) (4) (b) (4)	01 May 2021 09:48:18 29 Apr 2021 19:42:14
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Updated' (Site from System).	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:44:49
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). User entered '1'	System Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39 29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '23 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:44:36
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '26 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:44:36
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Not Applicable (NOT APPLICABLE)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '1'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered '0'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	29 Apr 2021 19:42:14
User entered 'Per medical records review, on 11/24/2020-11/25/2020 subject was hypoxic secondary to her history of asthma and COPD. This prolonged her hospitalization and thus is a new SAE. Con meds were given. Subject was stable at discharge.' reason for change: Data Entry Error User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 18:30:14
	Cassie Uminski (b) (4) (b) (4)	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 17:43:39

US3182192

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:35:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 17:43:39

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:35:05

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:50
DataPoint Verified.		22 Apr 2021 12:24:09
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:40:54

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:43:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:43:06
Data point term sent to Coder	System	12 Aug 2020 18:42:21
User entered 'Omeprazole'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Acid reflux'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '10'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:41:33
User entered 'un UNK 2009'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:41:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:43:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:43:06
Data point term sent to Coder	System	12 Aug 2020 18:42:21
User entered 'Citalopram'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Anxiety'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '40'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:41:58
User entered 'un UNK 2000'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:41:58
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:41:58

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:44:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:44:10
Data point term sent to Coder	System	12 Aug 2020 18:43:26
User entered 'Lisinopril'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Hypertension'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '20'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:42:27
User entered 'un UNK 2000'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:27
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:42:27

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:44:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:44:10
Data point term sent to Coder	System	12 Aug 2020 18:43:26
User entered 'Metoprolol'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Hypertension'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:53
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '25'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:53
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:53
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'twice daily (BID)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:53
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:42:53
User entered 'un UNK 2003'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:53
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:42:53
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:42:53

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:44:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:44:48
Data point term sent to Coder	System	12 Aug 2020 18:43:27
User entered 'Amlodipine'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:43:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:43:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Hypertension'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '10'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:43:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:43:21
User entered 'un UNK 2002'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:43:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:43:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:43:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:43:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:43:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:36:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:36:27
Data point term sent to Coder Coding entries removed.	System Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:36:03 25 Mar 2021 15:35:31
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:45:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:45:16
Data point term sent to Coder User entered 'Trelegy'	System Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:28 12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 13:19:10
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:35:31
User entered 'ASTHMA/Chronic Obstructive pulmonary Disease' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 15:35:31
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Asthma'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:05
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'puff (PUFF)'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:05
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:05
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:05
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:44:05
User entered 'un UNK 2014'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:05
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:05
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:44:05
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:44:05

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:46:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:46:13
Data point term sent to Coder User entered 'Albuterol'	System Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:29 12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Asthma'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '2'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'puff (PUFF)'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:51
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:44:36
User entered 'un UNK 2014'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:44:36
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:44:36

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User closed query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 06:25:46
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) (b) (4)	10 Sep 2020 15:23:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:23:40
Data point term sent to Coder	System	10 Sep 2020 15:22:39
Query 'Per DM CLR: Please provide brand name if known. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:22:07
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:22:03
User entered 'MULTIVITAMIN (unknown)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Sep 2020 15:22:03
User opened query 'Per DM CLR: Please provide brand name if known. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 08:14:19
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) (b) (4)	12 Aug 2020 18:46:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:46:13
Data point term sent to Coder	System	12 Aug 2020 18:45:29
User entered 'Multivitamin'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '2'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:45:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:45:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:04:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:45:04
User entered 'un UNK 2014'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:45:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:45:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:47:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:47:09
Data point term sent to Coder User entered 'Vitamin C'	System Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:46:31 12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '500'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'IU (IU)'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:45:47
User entered 'un UNK 2019'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:45:47
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:45:47

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:47:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:47:09
Data point term sent to Coder	System	12 Aug 2020 18:46:32
User entered 'Vitamin B12'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:46:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '1000'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:46:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'units'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:46:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:46:21
User entered 'un UNK 2019'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:46:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:46:21
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:46:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:46:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:46:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: VITAMIN K, PRODUCT: MENAQUINONE, PRODUCTSYNONYM: VITAMIN K2 [MENAQUINONE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Aug 2020 13:34:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 13:34:15
Data point term sent to Coder	System	12 Aug 2020 18:47:37
User entered 'Vitamin K2'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:47:14
User entered 'un UNK 2019'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:47:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:47:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:47:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
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) (b) (4)	02 Oct 2020 19:04:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:04:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHROMIUM;COPPER;FOLIC ACID;IODINE;IRON;LYCOPENE;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN D NOS;VITAMIN E NOS;XANTOXYL;ZINC, PRODUCTSYNONYM: CENTRUM WOMEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:18
Data point term sent to Coder	System	12 Aug 2020 18:48:37
User entered 'Centrum Women'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:44
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health maintenance'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:44
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '1'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:44
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:44
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:44
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:47:44
User entered 'un UNK 2005'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:47:44
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:47:44
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:47:44

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:18
Data point term sent to Coder	System	12 Aug 2020 18:48:38
User entered 'Vitamin D3'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:48:14
User entered 'un UNK 2009'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:14
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:48:14

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:19
Data point term sent to Coder	System	12 Aug 2020 18:49:39
User entered 'Glucosamine'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:46

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health maintenance'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:46

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:48:46
User entered 'un UNK 2009'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:46

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:48:46
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:48:46

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:48:46

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:48:46

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 18:48:46

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:50:19
Data point term sent to Coder	System	12 Aug 2020 18:49:42
User entered 'Zyrtec'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered '1'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:49:35
User entered 'un UNK 2005'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:49:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:49:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 18:52:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:52:08
Data point term sent to Coder User entered 'Claritin'	System Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:50:45 12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 11:05:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 18:50:04
User entered 'un UNK 2005'	Cassie Uminski (b) (4) (b) (4)	12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	12 Aug 2020 18:50:04
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:50:04

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 19:29:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:29:24
Data point term sent to Coder User entered 'Voltaren'	System Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:28:43 19 Oct 2020 19:27:49

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	19 Oct 2020 19:27:49

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Osteoarthritis'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '100'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'every other day (QOD)'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Topical (TOPICAL)'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '15 Sep 2020'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	19 Oct 2020 19:27:49
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 19:27:49

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 19:27:49

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 19:27:49

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
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)	13 Nov 2020 16:27:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Nov 2020 16:27:01
Data point term sent to Coder	System	13 Nov 2020 16:26:19
User entered 'Influenza Vaccine'	Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '1'	Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'injection'	Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'once (ONCE)'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '26 Oct 2020'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '26 Oct 2020'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User entered empty.	System	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User entered empty.	System	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:47
User entered empty.	System	13 Nov 2020 16:25:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: AFRIN NASAL DECONGESTANT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 08:26:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:26:10
Data point term sent to Coder	System	01 Mar 2021 18:43:51
Data point term sent to Coder	System	01 Mar 2021 13:41:08
User entered 'Afrin nasal spray'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'NOSEBLEED (epistaxis)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:42:53
User entered 'Nosebleed'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '2'	Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Other (OTHER)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Sprays'	Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '26 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '29 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User entered empty.	System	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User entered empty.	System	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:49
User entered empty.	System	01 Mar 2021 13:40:45

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 13:42:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:42:56
Data point term sent to Coder	System	01 Mar 2021 13:42:08
User entered 'Hydrocortisone'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:41:15

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Hemorrhoids'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '25'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Rectal (RECTAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'un UNK 2012'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:41:15
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:41:15

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:41:15

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:41:15

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 13:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:43:50
Data point term sent to Coder	System	01 Mar 2021 13:43:09
User entered 'Miralax'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:42:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Stool softener/Constipation prophylaxis'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '17'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'g (g)'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please clarify as page 5 of fax has 23Aug2020. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 20:04:45
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
Query 'Please clarify as page 5 of fax has 23Aug2020. ' answered with 'confirmed and updated' (Site from CRA).	Jennifer Gaston (b) (4)	26 Apr 2021 17:03:33
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 17:03:16
User entered '23 Aug 2020' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	26 Apr 2021 17:03:16
User opened query 'Please clarify as page 5 of fax has 23Aug2020. ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 16:41:40
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '23 Nov 2020'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:42:33
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 13:42:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 13:42:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 13:42:33

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Mar 2021 13:43:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Mar 2021 13:43:49
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 13:43:09
User entered 'Zolpidem'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Insomnia'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '10'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'other (OTHER)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'QPM'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'un UNK 2019'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:08
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:43:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:43:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:43:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA-3 FATTY ACIDS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:27:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:27:36
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
Data point term sent to Coder User entered 'Omega 3 acid'	System Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:44:10 01 Mar 2021 13:43:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Health Maintenance'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '1000'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'mg (mg)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'once daily (QD)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '23 Nov 2020'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:43:35
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 13:43:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 13:43:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 13:43:35

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 13:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:44:49
Data point term sent to Coder	System	01 Mar 2021 13:44:11
User entered 'Acetaminophen'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Septoplasty pain'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '650'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '23 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '01 Dec 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User entered empty.	System	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User entered empty.	System	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:23:55
User entered empty.	System	01 Mar 2021 13:44:08

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 13:45:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:45:49
Data point term sent to Coder	System	01 Mar 2021 13:45:12
User entered 'Hydrocodone/Acetaminophen'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Septoplasty Pain'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '5/325'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'as needed (PRN)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '23 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '01 Dec 2020'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User entered empty.	System	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User entered empty.	System	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:01
User entered empty.	System	01 Mar 2021 13:44:51

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Mar 2021 13:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 13:46:49
Data point term sent to Coder	System	01 Mar 2021 13:46:13
User entered 'Clonazepam'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Anxiety'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Please clarify if this should be 1.5 instead of 0.5. Pages 5 and 114 of fax. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 20:05:11
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
Query 'Please clarify if this should be 1.5 instead of 0.5. Pages 5 and 114 of fax. ' answered with 'confirmed and updated' (Site from CRA).	Jennifer Gaston (b) (4)	26 Apr 2021 17:05:13
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 17:04:49
User entered '1.5' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	26 Apr 2021 17:04:49
User opened query 'Please clarify if this should be 1.5 instead of 0.5. Pages 5 and 114 of fax. ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 16:45:05
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0.5'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please clarify as page 5 of fax has 13May2020. ' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 12:20:28
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
Query 'Please clarify as page 5 of fax has 13May2020. ' answered with 'confirmed and updated' (Site from CRA).	Jennifer Gaston (b) (4)	26 Apr 2021 17:06:23
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 17:05:51
User entered '13 May 2020' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	26 Apr 2021 17:05:51
User opened query 'Please clarify as page 5 of fax has 13May2020. ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 16:45:45
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '23 Nov 2020'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:45:16
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:45:16

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 18:40:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 18:40:41
Data point term sent to Coder Coding entries removed.	System Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:09:00 26 Apr 2021 17:08:19
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:29:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:29:44
Data point term sent to Coder	System	01 Mar 2021 13:46:12
User entered 'Sodium Chloride'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:46:02

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Post septoplasty prophylactic'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '1'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Spray'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'as needed (PRN)'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Should this be nasal instead of respiratory?' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 20:05:37
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
Query 'Should this be nasal instead of respiratory?' answered with 'confirmed and updated' (Site from CRA).	Jennifer Gaston (b) (4)	26 Apr 2021 17:08:40
Signature has been broken.	Jennifer Gaston (b) (4)	26 Apr 2021 17:08:19
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Jennifer Gaston (b) (4)	26 Apr 2021 17:08:19
User opened query 'Should this be nasal instead of respiratory?' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 16:52:29
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '24 Nov 2020'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:46:02
	(b) (4)	

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:46:02

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:46:02

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 13:46:02

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:05:54
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 Mar 2021 08:05:54
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
Data point term sent to Coder	System	01 Mar 2021 13:47:14
User entered 'Ondansetron'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Prophylacitc'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '4'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'other (OTHER)'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Continuous'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '22 Nov 2020'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '23 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User entered empty.	System	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User entered empty.	System	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:08
User entered empty.	System	01 Mar 2021 13:47:06

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:46:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:46:48
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:35:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:12:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:12:42
Data point term sent to Coder	System	01 Mar 2021 13:48:14
User entered 'Sodium Chloride 0.5%'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Prophylacitc'	Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '500'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'mL (mL)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'other (OTHER)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Continuous'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '22 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '23 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User entered empty.	System	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User entered empty.	System	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:14
User entered empty.	System	01 Mar 2021 13:48:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Mar 2021 13:51:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Mar 2021 13:51:49
Data point term sent to Coder	System	01 Mar 2021 13:51:15
User entered 'Ferrous Sulfate'	Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Anemia'	Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '325'	Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'twice daily (BID)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '26 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '10 Dec 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	Cassie Uminski (b) (4)	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User entered '2'	System	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User entered '1'	System	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:12
User entered '804 (804)'	System	01 Mar 2021 13:50:50

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 07:40:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:40:18
Data point term sent to Coder	System	01 Mar 2021 18:44:52
User entered 'Doxycycline'	Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Prophylaxis septoplasty'	(b) (4) Cassie Uminski (b) (4) (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '75'	Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'mg (mg)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'once daily (QD)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'Oral (ORAL)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '11 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '0'	Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered '21 Nov 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:22
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User entered '1'	System	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User entered '1'	System	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:24:20
User entered '804 (804)'	System	01 Mar 2021 18:44:07

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Apr 2021 17:28:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 17:28:49
Data point term sent to Coder	System	26 Apr 2021 17:27:22
User entered 'Omnipaque'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'CTA of Head and Neck'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered '350'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'mL (mL)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'once (ONCE)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'Other (OTHER)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'Injection'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
User entered '23 Nov 2020'	Jennifer Gaston (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered '0'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
User entered '23 Nov 2020'	Jennifer Gaston (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'No (N)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User entered empty.	System	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User entered empty.	System	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:35:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:19
User entered empty.	System	26 Apr 2021 17:27:21

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:35:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:09:50
DataPoint Verified.		22 Apr 2021 12:24:21
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User closed query 'Should this be yes as they had nasal surgery to repair the deviated septum?' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:01:43
Query 'Should this be yes as they had nasal surgery to repair the deviated septum?' answered with 'Updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:46:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:43:48
User opened query 'Should this be yes as they had nasal surgery to repair the deviated septum?' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:27:55
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	12 Feb 2021 02:50:47
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Jan 2021 17:52:26

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered '22 Nov 2020'	Jennifer Gaston (b) (4)	01 Mar 2021 00:44:33
	(b) (4)	

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered 'EKG'	Jennifer Gaston (b) (4)	01 Mar 2021 00:44:33
	(b) (4)	

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4)	01 Mar 2021 00:44:33
	(b) (4)	

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered empty.	Jennifer Gaston (b) (4)	01 Mar 2021 00:44:33
	(b) (4)	

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '11 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	01 Mar 2021 00:45:10

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Septoplasty'	Jennifer Gaston (b) (4)	01 Mar 2021 00:45:10

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Medical History (MH)'	Jennifer Gaston (b) (4)	01 Mar 2021 00:45:10

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:16
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	Jennifer Gaston (b) (4)	01 Mar 2021 00:45:10

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered '24 Oct 2020'	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:28:50

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'COVID Test'	Cassie Uminski (b) (4)	01 Mar 2021 13:28:50

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered 'Diagnostic (DIAGNOSTIC)'	Cassie Uminski (b) (4)	01 Mar 2021 13:28:50

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
User entered empty.	(b) (4) Cassie Uminski (b) (4)	01 Mar 2021 13:28:50

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '23 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:08:39

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'CT Scan'	Jennifer Gaston (b) (4)	25 Mar 2021 17:08:39

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4)	25 Mar 2021 17:08:39

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:08:39

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:47
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '22 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:08:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:47
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'CT Scan'	Jennifer Gaston (b) (4)	25 Mar 2021 17:08:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:47
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4)	25 Mar 2021 17:08:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:47
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	Jennifer Gaston (b) (4)	25 Mar 2021 17:08:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:50
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered '22 Nov 2020'	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:09:29

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:50
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Labwork'	Jennifer Gaston (b) (4)	25 Mar 2021 17:09:29

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:50
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4)	25 Mar 2021 17:09:29

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:50
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:19:10
User entered empty.	(b) (4) Jennifer Gaston (b) (4) (b) (4)	25 Mar 2021 17:09:29

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:54
DataPoint Verified.		29 Apr 2021 19:04:17
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
User entered '25 Nov 2020'	(b) (4) Jennifer Gaston (b) (4)	26 Apr 2021 17:19:30
	(b) (4)	

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:54
DataPoint Verified.	(b) (4)	29 Apr 2021 19:04:17
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'Echocardiogram'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:19:30

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:54
DataPoint Verified.		29 Apr 2021 19:04:17
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:19:30

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:54
DataPoint Verified.		29 Apr 2021 19:04:17
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:19:30

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:58
User signature succeeded.	Toby Briskin (b) (4)	26 Apr 2021 19:09:30
User entered '11 Nov 2020'	Jennifer Gaston (b) (4)	26 Apr 2021 17:19:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:58
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'Chest X-Ray'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:19:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:58
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:19:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:39:58
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:19:58

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:35:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:04
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered '23 Nov 2020'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:24:29

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:35:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:04
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'CTA of Head and Neck'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:24:29

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:35:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:04
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:24:29

US3182192

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:35:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:40:04
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	26 Apr 2021 19:09:30
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	26 Apr 2021 17:24:29

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
User entered '30/Nov/2020 12:09'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered '1'		30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
User entered '04/Dec/2020 14:42'	System	04 Dec 2020 14:42:42

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:44:58
DataPoint Verified.		08 Dec 2020 17:11:08
User entered '1'		04 Dec 2020 14:42:42

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:18:42
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered '08/Dec/2020 18:45'	System	08 Dec 2020 18:45:07

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:18:42
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 21:01:05
User entered '1'		08 Dec 2020 18:45:07

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:18:48
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered '08/Jan/2021 16:01'	System	08 Jan 2021 21:01:16

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:18:48
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:38:38
User entered '1'		08 Jan 2021 21:01:16

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:18:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered '01/Mar/2021 09:38'	System	01 Mar 2021 15:38:49

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:18:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:27:04
User entered '1'		01 Mar 2021 15:38:49

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:19:03
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
	(b) (4)	
User entered '05/Mar/2021 11:26'	System	05 Mar 2021 16:27:00

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:19:03
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:27:04
User entered 'l'		05 Mar 2021 16:27:00

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	[REDACTED]	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:19:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
	(b) (4)	
User entered '26/Mar/2021 10:38'	System	26 Mar 2021 15:38:04

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:22:19
DataPoint Verified.		30 Mar 2021 19:19:09
User signature succeeded.	Mary Beth Manning	26 Mar 2021 16:05:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:38:04

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:35
User entered '08/Apr/2021 13:22'	(b) (4) System	08 Apr 2021 13:22:34

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:26:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
User signature succeeded.	Toby Briskin (b) (4)	08 Apr 2021 17:15:35
User entered 'l'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:22:34

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	System	02 Apr 2021 15:28:56
	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 12:38:32
User signature succeeded.	Toby Briskin (b) (4)	28 Apr 2021 09:14:06
User entered '26/Apr/2021 16:22'	System	26 Apr 2021 20:22:33

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:26:06
DataPoint Verified.	[REDACTED]	28 Apr 2021 12:38:32
User signature succeeded.	Toby Briskin (b) (4)	28 Apr 2021 09:14:06
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 20:22:33

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:33
Un-reviewed for Safety.		04 Dec 2020 14:42:30
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'USA-US075-2020-MRNA-1273-P301000005'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'Yes (Y)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'No (N)'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Toby'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:11
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Jennifer'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.	(b) (4)	08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
Un-reviewed for Safety.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 15:28:56
User entered 'Briskin'	System	02 Apr 2021 15:28:56
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:14
DataPoint Verified.	(b) (4)	08 Dec 2020 17:11:08
Reviewed for Safety.	(b) (4)	30 Nov 2020 17:08:58
User entered 'Gaston'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered 'Beachwood'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		30 Nov 2020 17:08:58
User entered 'OH'	System	30 Nov 2020 17:08:46

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:38:09
Reviewed for Safety.		08 Apr 2021 13:22:19
User signature succeeded.	Toby Briskin (b) (4)	05 Apr 2021 18:21:43
User entered '44122'	(b) (4) System	02 Apr 2021 15:28:56

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:11:08
Reviewed for Safety.		04 Dec 2020 14:42:12
User entered 'US'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:35:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	30 Apr 2021 13:26:22
User entered '9'	System	26 Apr 2021 20:22:33
User entered '8'	System	08 Apr 2021 13:22:34
User entered '7'	System	26 Mar 2021 15:38:04
User entered '6'	System	05 Mar 2021 16:27:00
User entered '5'	System	01 Mar 2021 15:38:49
User entered '4'	System	08 Jan 2021 21:01:16
User entered '3'	System	08 Dec 2020 18:45:07
User entered '2'	System	04 Dec 2020 14:42:42
User entered '1'	System	30 Nov 2020 17:09:08

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:35:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	30 Apr 2021 20:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:16:25
User entered '30/Apr/2021 06:26'	System	30 Apr 2021 13:26:22

US3182192

Folder: SAE USA-US075-2020-MRNA-1273-P301000005

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:35:05

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.

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	30 Apr 2021 20:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:16:25
User entered '1'		30 Apr 2021 13:26:22