

US3512199 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:49:49

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US3512199

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

[Participant ID](#)

US3512199

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

US3512199

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 SEP 2020

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

Folder OID SCRN

US3512199

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" 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) 12 Feb 2021 21:38:13

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Date of Informed Consent (*dd MMM yyyy*) 02 SEP 2020

Month and Year of Informed Consent (derived) SEP 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

US3512199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:38:14

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Condition	LEFT RETINAL DETACHMENT
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 (3)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Condition	INTRAVENTRICULAR BRAIN BLEED
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 (4)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	(b) (6) 1961
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1961
Start Year (derived)	1961
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512199

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Condition	CUT ON LEFT KNEE
Start date (dd MMM yyyy)	25 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	25 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Condition	ONE STITCH PLACED FROM LEFT KNEE CUT
Start date (dd MMM yyyy)	25 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	25 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 02 SEP 2020

Time of assessment (*00:00-23:59*) 15:36 (24 HR)

Vital Signs Date and Time (derived) 02 SEP 2020 15:36

Height (*xxx.x*) 71 in

Weight (*xxx.x*) 198.2 lb

BMI (*xxx.x*) 27.70109 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3512199

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3512199

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:38:14

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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

MAINTENANCE WORK

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) 12 Feb 2021 21:38:14

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

US3512199

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 SEP 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145011

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk
 >=18 and <65 years and at risk
 >=65 years

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes No

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes No

Severe obesity (body mass index > or = 40kg/m2) Yes No

Diabetes (Type I, Type 2, or gestational) Yes No

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Height	ND - Not Done
Weight	ND - Not Done

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

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>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:36 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:36
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

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>)	02 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	17:15 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 17:15
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3512199

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

02 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 16:44 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 16:44

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

US3512199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	02 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:13 (24 HR)
Collection date and time (derived)	02 SEP 2020 16:13

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Collection date (<i>dd MMM yyyy</i>)			02 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	16:00	02 SEP 2020 16:00
Nasopharyngeal Swab 2	No		

US3512199

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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 02 SEP 2020 17:20

PC Open Date & Time 02 SEP 2020 17:04

PC Close Date & Time 02 SEP 2020 19:34

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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 97.8 °F

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

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

PC Time Stamp 02 SEP 2020 20:31
PC Open Date & Time 02 SEP 2020 20:29
PC Close Date & Time 03 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

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	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 SEP 2020 17:19
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

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	98.1 °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	04 SEP 2020 20:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

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	05 SEP 2020 20:14
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 97.7 °F

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

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

PC Time Stamp 06 SEP 2020 21:28

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

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	98.2 °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	07 SEP 2020 21:28
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F** 98.2 °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):

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

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

PC Time Stamp 08 SEP 2020 22:39

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °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 SEP 2020 05:46
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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	02 SEP 2020 17:20
PC Open Date & Time	02 SEP 2020 17:04
PC Close Date & Time	02 SEP 2020 19:34

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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	02 SEP 2020 20:31
PC Open Date & Time	02 SEP 2020 20:29
PC Close Date & Time	03 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

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	03 SEP 2020 17:19
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

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

04 SEP 2020 20:17

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

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	05 SEP 2020 20:14
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

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	06 SEP 2020 21:29
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

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	07 SEP 2020 21:28
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

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

08 SEP 2020 22:40

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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

No

Yes

PC Time stamp	02 SEP 2020 17:22
PC Open Date & Time	02 SEP 2020 17:04
PC Close Date & Time	02 SEP 2020 19:34

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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

No

Yes

PC Time stamp	02 SEP 2020 20:32
PC Open Date & Time	02 SEP 2020 20:29
PC Close Date & Time	03 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

	Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 17:20
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 20:17
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 20:15
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 21:30
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 21:29
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 22:41
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3512199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 05:46
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3512199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

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>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:06 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:06
Temperature (<i>xxx.x</i>)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	175 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Timepoint Pre-Dose
Post-Dose

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

Time of assessment (*00:00-23:59*) _____

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

US3512199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

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? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3512199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	15:30 (24 HR)
Collection date and time (derived)	30 SEP 2020 15:30

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Collection date (<i>dd MMM yyyy</i>)			30 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	15:12	30 SEP 2020 15:12
Nasopharyngeal Swab 2	No		

US3512199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 7 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 30 OCT 2020

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

Folder OID VISIT3

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 14:35
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

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.

US3512199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 30 OCT 2020

Collection time (*00:00-23:59*) 14:43 (24 HR)

Collection date and time (derived) 30 OCT 2020 14:43

US3512199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:14

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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 02 NOV 2020 07:12:28

Patient Cloud Open Date & Time 02 NOV 2020 00:01

Patient Cloud Close Date & Time 06 NOV 2020 23:59

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	09 NOV 2020 07:56:27
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 10:32:36
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 82

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#) 24 NOV 2020 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 08:34:27
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 96

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

No

Yes

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

No

Yes

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

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

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

Date and time of submission 06 DEC 2020 12:46:23

Patient Cloud Open Date & Time 04 DEC 2020 00:01

Patient Cloud Close Date & Time 08 DEC 2020 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 11 DEC 2020 07:20:17

Patient Cloud Open Date & Time 11 DEC 2020 00:01

Patient Cloud Close Date & Time 15 DEC 2020 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 21 DEC 2020 17:59:50

Patient Cloud Open Date & Time 18 DEC 2020 00:01

Patient Cloud Close Date & Time 22 DEC 2020 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 12:37:36
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 10:35:12
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	11 JAN 2021 17:59:58
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	18 JAN 2021 08:12:59
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 12:01:33
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 31 JAN 2021 12:00:39

Patient Cloud Open Date & Time 29 JAN 2021 00:01

Patient Cloud Close Date & Time 02 FEB 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 05 FEB 2021 09:04:09

Patient Cloud Open Date & Time 05 FEB 2021 00:01

Patient Cloud Close Date & Time 09 FEB 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	14 FEB 2021 12:01:12
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 19 FEB 2021 08:54:28

Patient Cloud Open Date & Time 19 FEB 2021 00:01

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 08:29:52
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	05 MAR 2021 08:36:45
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 10:53:50
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	19 MAR 2021 08:16:01
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 12:52:00
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	02 APR 2021 07:42:21
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	09 APR 2021 12:03:01
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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	18 APR 2021 12:00:54
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 16:18:23
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 10:58:37
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#) 08 JUN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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°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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 07 DEC 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 28 DEC 2021 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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°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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#) 01 FEB 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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°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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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°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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

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

[Patient Cloud Close Date & Time](#) 05 JUL 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#) 20 SEP 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3512199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:49:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 08:37:08

US3512199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 20:01:08

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 20:01:08

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 APR 2021

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

Folder OID VISIT4

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3512199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

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.

US3512199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 09 APR 2021

Collection time (*00:00-23:59*) 13:12 (24 HR)

Collection date and time (derived) 09 APR 2021 13:12

US3512199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:04:42

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:04:42

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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 _____

US3512199

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3512199

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Date of Contact _____

Time of Contact _____

Date and Time of Contact (derived) _____

Type of Contact

Clinic Visit - Scheduled

Clinical Visit - Unscheduled

Safety Call

Convalescent Tele-visit

Has the subject reported symptoms of SARS-COV-2? Yes

No

US3512199

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

[Generate Next COVID-19 Assessment](#)

Yes
No

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:25:39

Generated On: 11 Aug 2021 22:49:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 FEB 2021

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

Folder OID UNBLND_DECIDE

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 12:50:36

Generated On: 11 Aug 2021 22:49:49

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" 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

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 21:25:39

Generated On: 11 Aug 2021 22:49:49

Height	71 in
Weight	192.6 lb
BMI (xxx.x)	26.91841

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:25:39

Generated On: 11 Aug 2021 22:49:49

Height	71 in
Weight	192.6 lb
BMI (xxx.x)	26.91841
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)	12 FEB 2021
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 14:43
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:25:39

Generated On: 11 Aug 2021 22:49:49

Height	71 in
Weight	192.6 lb
BMI (xxx.x)	26.91841
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)	12 FEB 2021
Time of assessment (00:00-23:59)	16:37 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 16:37
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:25:38

Generated On: 11 Aug 2021 22:49:49

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:25:38

Generated On: 11 Aug 2021 22:49:49

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) 12 FEB 2021

What was the treatment time? (00:00-23:59) 16:06 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 16:06

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

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:25:38

Generated On: 11 Aug 2021 22:49:49

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 FEB 2021

Collection time (*00:00-23:59*) 14:20 (24 HR)

Collection date and time (derived) 12 FEB 2021 14:20

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 21:25:38

Generated On: 11 Aug 2021 22:49:49

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 FEB 2021

Collection time (*00:00 - 23:59*) 14:17

Collection Date and Time (derived) 12 FEB 2021 14:17

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:25:38

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 20:01:08

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 20:01:08

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3512199

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

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>)	12 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:13 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 14:13
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>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

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>)	12 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:15 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 15:15
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*)

12 MAR 2021

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

US3512199

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

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) 12 MAR 2021

What was the treatment time? (00:00-23:59) 14:44 (24 HR)

Treatment Date and Time (derived) 12 MAR 2021 14:44

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

US3512199

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 14:25:55

Generated On: 11 Aug 2021 22:49:49

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3512199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 14:25:55

Generated On: 11 Aug 2021 22:49:49

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512199

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 APR 2021

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

Folder OID OLD57

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) _____

Time of assessment (*00:00-23:59*) _____

Vital Signs Date and Time (derived) _____

Temperature (*xxx.x*) _____

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) _____

Pulse units _____

Respiratory Rate (*xxx*) _____

Respiratory Rate units _____

Systolic Blood Pressure (*xxx*) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (*xxx*) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3512199

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

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.

US3512199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 16:44:44

Generated On: 11 Aug 2021 22:49:49

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 09 APR 2021

Collection time (*00:00-23:59*) 13:12 (24 HR)

Collection date and time (derived) 09 APR 2021 13:12

US3512199

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

AEID

Adverse event

WORSENING RIGHT SHOULDER
SORENESS SECONDARY TO
YARD WORK

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) 8 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 8 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

AEID	
Adverse event	ASYMPTOMATIC COVID-19 INFECTION
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	2 SEP 2020
Start time (00:00-23:59)	16:00 (24 HR)
AE start date and time (derived)	2 SEP 2020 16:00
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	12 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:44:27

Generated On: 11 Aug 2021 22:49:49

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication LEVOTHYROXINE

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

Dose per administration 175

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication NICARDIPINE

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 60

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication FENOFIBRIC ACID

Prophylaxis Yes
No

Indication HIGH TRIGLYCERIDES

Dose per administration 135

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) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

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

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication LIVALO

Prophylaxis Yes
No

Indication HIGH CHOLESTEROL

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 (4)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication METOPROLOLOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

TAKES 2 TABS IN THE
MORNING AND 1 TAB IN THE
EVENING.

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

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

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication METFORMIN

Prophylaxis Yes
No

Indication TYPE 2 DIABETES

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
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

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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 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) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication TRULICITY

Prophylaxis Yes
No

Indication TYPE 2 DIABETES

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 MAY 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication GLIMEPIRIDE

Prophylaxis Yes
No

Indication TYPE 2 DIABETES

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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US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 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) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication PROPHYLAXIS FOR CORONARY
ARTERY DISEASE

Dose per administration 81

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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US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication ALEVE

Prophylaxis Yes
No

Indication WORSENING RIGHT SHOULDER SORENESS SECONDARY TO YARD WORK

Dose per administration 220

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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US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

	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) 8 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 8 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication SEASONAL INFLUENZA

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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US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

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*) 16 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 16 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Name of Medication ALEVE

Prophylaxis Yes
No

Indication RIGHT SHOULDER PAIN

Dose per administration 220

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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US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3512199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 22:43:03

Generated On: 11 Aug 2021 22:49:49

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3512199

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Feb 2021 21:38:13

Generated On: 11 Aug 2021 22:49:49

Date of dosing discontinuation (dd MMM yyyy) 30 SEP 2020

Primary reason for dosing discontinuation

- AE (specify)
- SAE (specify)
- Death
- Lost To Follow-up
- Physician decision (specify)
- Pregnancy
- Protocol deviation (specify)
- Study Terminated By Sponsor
- Withdrawal of consent by participant (specify)
- Due to SARS-COV-2
- Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify _____

US3512199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:49

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

Audit

US3512199 (Prod: Jacksonville Center for Clinical Research Center)

US3512199

Form: Participant Creation

Generated On: 11 Aug 2021 22:49:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'US3512199'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:39:31

US3512199

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:25

US3512199

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:39:32

US3512199

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Clinic (Clinic)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:25

US3512199

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'SCRN'	System	02 Sep 2020 20:52:25

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:39:33

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '59'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'YEARS'	System	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '59'	System	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Male (M)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '1'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:40

US3512199

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:52:40
	(b) (4)	

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:52:58
	(b) (4)	

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Sep 2020'	System	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2020'	System	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Amendment 3 (3)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:53:06
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Was participant enrolled in the study is No, however reason for screen fail is missing. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 20:53:06
User opened query 'Was participant enrolled in the study is No, however reason for screen fail is missing. Please provide.' (Site from System).	System	02 Sep 2020 20:52:58
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:53:11
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:52:58

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 20:53:11
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	02 Sep 2020 20:52:58
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:39:32

US3512199

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '1'	System	02 Sep 2020 20:53:18

US3512199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:49:49

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:53:18

US3512199

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:49:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:41:19

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 19:04:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 19:04:55
Data point term sent to Coder	System	01 Oct 2020 19:04:16
Coding entries removed.	Brenda Anderson (b) (4)	01 Oct 2020 19:03:26
User entered 'FARSIGHTED bilateral' reason for change: Data Entry Error	Brenda Anderson (b) (4)	01 Oct 2020 19:03:26
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:42:49
Data point term sent to Coder	System	02 Sep 2020 21:41:54
User entered 'FARSIGHTED'	Allison Crain (b) (4)	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2018'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2018'	System	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2018'	System	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:41:35

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal detachment, LLT: Retinal detachment - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 19:04:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 19:04:55
Data point term sent to Coder	System	01 Oct 2020 19:04:17
Coding entries removed.	Brenda Anderson (b) (4)	01 Oct 2020 19:04:08
User entered 'left RETINAL DETACHMENT' reason for change: Data Entry Error	Brenda Anderson (b) (4)	01 Oct 2020 19:04:08
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal detachment, LLT: Retinal detachment - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:43:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:43:52
Data point term sent to Coder	System	02 Sep 2020 21:42:55
User entered 'RETINAL DETACHMENT'	Allison Crain (b) (4)	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2008'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2008'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2008'	System	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2008'	System	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2008'	System	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2008'	System	02 Sep 2020 21:41:59

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Intraventricular haemorrhage, LLT: Intraventricular bleeding - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 21:25:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 21:25:53
Data point term sent to Coder	System	02 Sep 2020 21:42:55
User entered 'INTRAVENTRICULAR BRAIN BLEED'	Allison Crain (b) (4)	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2008'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2008'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2008'	System	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2008'	System	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2008'	System	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2008'	System	02 Sep 2020 21:42:21

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:43:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:43:52
Data point term sent to Coder	System	02 Sep 2020 21:42:55
User entered 'TYPE 2 DIABETES'	Allison Crain (b) (4)	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2010'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2010'	System	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2010'	System	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:42:43

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Investigations, HLT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 21:43:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 21:43:51
Data point term sent to Coder	System	02 Sep 2020 21:42:57
User entered 'HIGH CHOLESTEROL'	Allison Crain (b) (4)	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2010'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2010'	System	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2010'	System	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:42:56

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Investigations, HLG: Lipid analyses, HLT: Triglyceride analyses, PT: Blood triglycerides increased, LLT: Triglycerides high - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:44:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:44:54
Data point term sent to Coder	System	02 Sep 2020 21:43:58
User entered 'HIGH TRIGLYCERIDES'	Allison Crain (b) (4)	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2010'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2010'	System	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2010'	System	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:43:10

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:45:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:45:03
Data point term sent to Coder	System	02 Sep 2020 21:43:59
User entered 'HYPOTHYROIDISM'	Allison Crain (b) (4)	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	04 Sep 2020 22:16:01
User entered (b) (6) 1961' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	04 Sep 2020 22:16:01
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	02 Sep 2020 21:43:31
User entered 'UN UNK 1961'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered (b) (6) 1961'	System	04 Sep 2020 22:16:01
User entered (b) (6) 1961'	System	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '1961'	System	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:43:31

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:46:49
Data point term sent to Coder	System	02 Sep 2020 21:46:06
User entered 'HYPERTENSION'	Allison Crain (b) (4)	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2010'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2010'	System	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2010'	System	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:45:40

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
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)	02 Sep 2020 21:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 21:46:49
Data point term sent to Coder	System	02 Sep 2020 21:46:07
User entered 'INSOMNIA'	Allison Crain (b) (4)	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 1966'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 1966'	System	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '1966'	System	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:45:51

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of leg - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 08:47:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 08:47:42
Data point term sent to Coder	System	02 Sep 2020 21:48:15
User entered 'CUT ON LEFT KNEE'	Allison Crain (b) (4)	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '25 Jun 2020'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '25 Jun 2020'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:47:19
	(b) (4)	

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jun 2020'	System	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2020'	System	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jun 2020'	System	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2020'	System	02 Sep 2020 21:47:19

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Surgical and medical procedures, HLG: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Suture insertion, LLT: Suture insertion - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 11:26:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 11:26:53
Data point term sent to Coder	System	02 Sep 2020 21:48:17
User entered 'ONE STITCH PLACED FROM LEFT KNEE CUT'	Allison Crain (b) (4)	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '25 Jun 2020'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '25 Jun 2020'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jun 2020'	System	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2020'	System	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jun 2020'	System	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2020'	System	02 Sep 2020 21:48:12

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Tobacco user - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 21:50:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 21:50:55
Data point term sent to Coder	System	02 Sep 2020 21:49:18
User entered 'CURRENT TOBACCO USE'	Allison Crain (b) (4)	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 1990'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 1990'	System	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '1990'	System	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	02 Sep 2020 21:48:49

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 12:46:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 12:46:45
Data point term sent to Coder	System	12 Nov 2020 12:46:18
User entered 'right shoulder pain'	Brenda Anderson (b) (4)	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'un UNK 2018'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'Jan 2018'	System	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '2018'	System	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:49:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered empty.	System	12 Nov 2020 12:45:56

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '15:36'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '02 Sep 2020 15:36'	System	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '71' in reason for change: Data Entry Error	Allison Crain (b) (4)	08 Sep 2020 17:28:40
	(b) (4)	
User entered '71' cm	Taylor Johnson (b) (4)	02 Sep 2020 20:54:44
	(b) (4)	
DataPoint set to visible.	System	02 Sep 2020 20:53:18

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '198.2' lb	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:54:44
DataPoint set to visible.	(b) (4) System	02 Sep 2020 20:53:18

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered '27.70109'	System	08 Sep 2020 17:28:40
User entered '178.71634'	System	02 Sep 2020 20:54:44
DataPoint set to visible.	System	02 Sep 2020 20:53:18

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'kg/m2'	System	02 Sep 2020 20:54:44
DataPoint set to visible.	System	02 Sep 2020 20:53:18

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'bpm'	System	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'breaths/min'	System	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'mmHg'	System	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User entered 'mmHg'	System	02 Sep 2020 20:54:44

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05

US3512199

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05

US3512199

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:54:54

US3512199

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:54:54
	(b) (4)	

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:30
	(b) (4)	

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'maintenance work'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

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)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '1'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '1'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:07:05
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'routinely goes to places where people gather'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:30

US3512199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:56:44

US3512199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:44
	(b) (4)	

US3512199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Clinic (Clinic)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:56:44

US3512199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'VISIT1'	System	02 Sep 2020 20:56:44

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:04:27

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '145011'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:04:27

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:04:27

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:58:25

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:58:25

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:58:25

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:58:25

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:58:25

US3512199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:49

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:09:24
User entered 'No (N)'	Brenda Anderson (b) (4)	04 Nov 2020 14:46:47
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Amendment Manager: DataPoint set to visible.	(b) (4), (b) (6)	04 Nov 2020 14:46:37
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	03 Nov 2020 14:57:33
	System	19 Sep 2020 04:59:54
	System	19 Sep 2020 04:59:53

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:59:45
	(b) (4)	

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '15:36'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '02 Sep 2020 15:36'	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '98.8' F	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (Oral)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:59:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '74'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'bpm'	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '16'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'breaths/min'	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '154'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '91'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 20:59:45
	(b) (4)	

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:29:31
User entered '17:15' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Sep 2020 17:29:31
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:59:45
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '02 Sep 2020 17:15'	System	08 Sep 2020 17:29:31
User entered empty.	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:29:31
User entered '98.0' F reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Sep 2020 17:29:31
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:59:45
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:29:36
User entered 'Oral (Oral)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Sep 2020 17:29:36
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:31
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:29:31
User entered '68' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Sep 2020 17:29:31
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:59:45
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'bpm'	System	08 Sep 2020 17:29:31
User entered empty.	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:29:31
User entered '16' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Sep 2020 17:29:31
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:59:45
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'breaths/min'	System	08 Sep 2020 17:29:31
User entered empty.	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:29:31
User entered '142' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Sep 2020 17:29:31
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:59:45
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	08 Sep 2020 17:29:31
User entered empty.	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:29:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:29:31
User entered '90' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	08 Sep 2020 17:29:31
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:59:45
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	08 Sep 2020 17:29:31
User entered empty.	System	02 Sep 2020 20:59:45

US3512199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:00:54

US3512199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:00:54
	(b) (4)	

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:04:02
	(b) (4)	

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:04:02
	(b) (4)	

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '16:44'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '02 Sep 2020 16:44'	System	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Left Arm (LEFT ARM)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'ONCE'	System	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 21:04:02

US3512199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:05:15

US3512199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:05:15
	(b) (4)	

US3512199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '16:13'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:05:15

US3512199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '02 Sep 2020 16:13'	System	02 Sep 2020 21:05:15

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '02 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '16:00'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '02 Sep 2020 16:00'	System	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	02 Sep 2020 21:05:45

US3512199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:05:52

US3512199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	02 Sep 2020 21:05:52

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:19:13', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '06b1f253-793c-4ef6-a340-11e348a3026b' User entered 'Yes (Y)'	System	02 Sep 2020 21:20:12
	System	02 Sep 2020 21:20:12

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:19:28', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '06b1f253-793c-4ef6-a340-11e348a3026b' User entered '98.2'	System	02 Sep 2020 21:20:12
	System	02 Sep 2020 21:20:12

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:19:42', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '06b1f253-793c-4ef6-a340-11e348a3026b' User entered 'No (N)'	System	02 Sep 2020 21:20:12
	System	02 Sep 2020 21:20:12

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:20:09', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '06b1f253-793c-4ef6-a340-11e348a3026b' User entered '02 Sep 2020 17:20'	System	02 Sep 2020 21:20:12
	System	02 Sep 2020 21:20:12

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 17:04'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 19:34'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:29:32', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '3440289e-0b70-47bc-8b71-f0ccd64c68ab' User entered 'Yes (Y)'	System	03 Sep 2020 00:31:11
	System	03 Sep 2020 00:31:11

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:30:45', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '3440289e-0b70-47bc-8b71-f0ccd64c68ab' User entered '97.8'	System	03 Sep 2020 00:31:11
	System	03 Sep 2020 00:31:11

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:30:51', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '3440289e-0b70-47bc-8b71-f0ccd64c68ab' User entered 'No (N)'	System	03 Sep 2020 00:31:11
	System	03 Sep 2020 00:31:11

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:31:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '3440289e-0b70-47bc-8b71-f0ccd64c68ab' User entered '02 Sep 2020 20:31'	System	03 Sep 2020 00:31:11
	System	03 Sep 2020 00:31:11

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 20:29'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 2'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:18:59', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '0f95f768-3bdc-42b2-a9db-990914bdfe66'	System	03 Sep 2020 21:19:23
User entered 'Yes (Y)'	System	03 Sep 2020 21:19:23

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:09', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '0f95f768-3bdc-42b2-a9db-990914bdfe66' User entered '98.3'	System	03 Sep 2020 21:19:23
	System	03 Sep 2020 21:19:23

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:14', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '0f95f768-3bdc-42b2-a9db-990914bdfe66'	System	03 Sep 2020 21:19:23
User entered 'No (N)'	System	03 Sep 2020 21:19:23

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '0f95f768-3bdc-42b2-a9db-990914bdfe66'	System	03 Sep 2020 21:19:23
User entered '03 Sep 2020 17:19'	System	03 Sep 2020 21:19:23

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 3'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:15:42', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7c8bf91d-703f-47dd-929a-6ea8060289f7'	System	05 Sep 2020 00:16:53
User entered 'Yes (Y)'	System	05 Sep 2020 00:16:53

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:15:58', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7c8bf91d-703f-47dd-929a-6ea8060289f7' User entered '98.1'	System	05 Sep 2020 00:16:53
	System	05 Sep 2020 00:16:53

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:16:03', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7c8bf91d-703f-47dd-929a-6ea8060289f7'	System	05 Sep 2020 00:16:53
User entered 'No (N)'	System	05 Sep 2020 00:16:53

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:16:50', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7c8bf91d-703f-47dd-929a-6ea8060289f7'	System	05 Sep 2020 00:16:53
User entered '04 Sep 2020 20:16'	System	05 Sep 2020 00:16:53

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 4'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:01', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '80c208a1-b6a8-4fce-8ebd-134e6fc4a319' User entered 'Yes (Y)'	System	06 Sep 2020 00:14:28
	System	06 Sep 2020 00:14:28

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:14', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '80c208a1-b6a8-4fce-8ebd-134e6fc4a319' User entered '97.9'	System	06 Sep 2020 00:14:28
	System	06 Sep 2020 00:14:28

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:17', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '80c208a1-b6a8-4fce-8ebd-134e6fc4a319'	System	06 Sep 2020 00:14:28
User entered 'No (N)'	System	06 Sep 2020 00:14:28

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:24', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '80c208a1-b6a8-4fce-8ebd-134e6fc4a319'	System	06 Sep 2020 00:14:28
User entered '05 Sep 2020 20:14'	System	06 Sep 2020 00:14:28

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 5'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:28:29', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c7d41458-3e74-407c-a7d7-787c14c6f852' User entered 'Yes (Y)'	System	07 Sep 2020 01:28:54
	System	07 Sep 2020 01:28:54

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:28:39', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c7d41458-3e74-407c-a7d7-787c14c6f852' User entered '97.7'	System	07 Sep 2020 01:28:54
	System	07 Sep 2020 01:28:54

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:28:46', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c7d41458-3e74-407c-a7d7-787c14c6f852'	System	07 Sep 2020 01:28:54
User entered 'No (N)'	System	07 Sep 2020 01:28:54

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:28:50', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c7d41458-3e74-407c-a7d7-787c14c6f852'	System	07 Sep 2020 01:28:54
User entered '06 Sep 2020 21:28'	System	07 Sep 2020 01:28:54

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 6'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7a866207-7849-493f-8565-a3b7c6e417f3'	System	08 Sep 2020 01:28:26
User entered 'Yes (Y)'	System	08 Sep 2020 01:28:26

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:15', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7a866207-7849-493f-8565-a3b7c6e417f3' User entered '98.2'	System	08 Sep 2020 01:28:26
	System	08 Sep 2020 01:28:26

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:20', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7a866207-7849-493f-8565-a3b7c6e417f3'	System	08 Sep 2020 01:28:26
User entered 'No (N)'	System	08 Sep 2020 01:28:26

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:23', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7a866207-7849-493f-8565-a3b7c6e417f3'	System	08 Sep 2020 01:28:26
User entered '07 Sep 2020 21:28'	System	08 Sep 2020 01:28:26

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 7'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:39:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8902bbe9-db3d-4a3b-8a5f-85740d49cd4c' User entered 'Yes (Y)'	System	09 Sep 2020 02:39:48
	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:39:25', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8902bbe9-db3d-4a3b-8a5f-85740d49cd4c' User entered '98.2'	System	09 Sep 2020 02:39:48
	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:39:31', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8902bbe9-db3d-4a3b-8a5f-85740d49cd4c' User entered 'Yes (Y)'	System	09 Sep 2020 02:39:48
	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Contact was made and medication discussed' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 07:40:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:39:40', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8902bbe9-db3d-4a3b-8a5f-85740d49cd4c' User entered '1'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:08:45
	System	09 Sep 2020 02:39:48
	System	09 Sep 2020 02:39:48
	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:39:40', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8902bbe9-db3d-4a3b-8a5f-85740d49cd4c' User entered '0'	System	09 Sep 2020 02:39:48
	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:39:44', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8902bbe9-db3d-4a3b-8a5f-85740d49cd4c' User entered '08 Sep 2020 22:39'	System	09 Sep 2020 02:39:48
	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	09 Sep 2020 02:39:48
User entered 'Day 8'	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-10T05:46:24', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'bdecc820-270a-4910-8c73-71bc301bd91c' User entered 'Yes (Y)'	System	10 Sep 2020 23:36:47
	System	10 Sep 2020 23:36:47

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-10T05:46:32', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'bdecc820-270a-4910-8c73-71bc301bd91c' User entered '98.3'	System	10 Sep 2020 23:36:47
	System	10 Sep 2020 23:36:47

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-10T05:46:37', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'bdecc820-270a-4910-8c73-71bc301bd91c'	System	10 Sep 2020 23:36:47
User entered 'No (N)'	System	10 Sep 2020 23:36:47

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-10T05:46:40', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'bdecc820-270a-4910-8c73-71bc301bd91c' User entered '10 Sep 2020 05:46'	System	10 Sep 2020 23:36:47
	System	10 Sep 2020 23:36:47

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:20:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4dab11fa-7272-4dff-bf6b-67eaff1ac700'	System	02 Sep 2020 21:20:52
User entered 'None (1)'	System	02 Sep 2020 21:20:52

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:20:23', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4dab11fa-7272-4dff-bf6b-67eaff1ac700'	System	02 Sep 2020 21:20:52
User entered 'No (N)'	System	02 Sep 2020 21:20:52

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:20:27', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4dab11fa-7272-4dff-bf6b-67eaff1ac700'	System	02 Sep 2020 21:20:52
User entered 'No (N)'	System	02 Sep 2020 21:20:52

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:20:41', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4dab11fa-7272-4dff-bf6b-67eaff1ac700'	System	02 Sep 2020 21:20:52
User entered 'None (1)'	System	02 Sep 2020 21:20:52

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:20:47', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4dab11fa-7272-4dff-bf6b-67eaff1ac700'	System	02 Sep 2020 21:20:52
User entered '02 Sep 2020 17:20'	System	02 Sep 2020 21:20:52

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 17:04'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 19:34'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:31:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd7b16a65-39fb-4b32-afce-98f8243b1253'	System	03 Sep 2020 00:31:49
User entered 'None (1)'	System	03 Sep 2020 00:31:49

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:31:28', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd7b16a65-39fb-4b32-afce-98f8243b1253'	System	03 Sep 2020 00:31:49
User entered 'No (N)'	System	03 Sep 2020 00:31:49

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:31:31', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd7b16a65-39fb-4b32-afce-98f8243b1253'	System	03 Sep 2020 00:31:49
User entered 'No (N)'	System	03 Sep 2020 00:31:49

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:31:37', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd7b16a65-39fb-4b32-afce-98f8243b1253'	System	03 Sep 2020 00:31:49
User entered 'None (1)'	System	03 Sep 2020 00:31:49

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:31:47', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd7b16a65-39fb-4b32-afce-98f8243b1253'	System	03 Sep 2020 00:31:49
User entered '02 Sep 2020 20:31'	System	03 Sep 2020 00:31:49

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 20:29'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 2'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:26', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8d202023-13dd-45b0-a54b-48bf87373bf9'	System	03 Sep 2020 21:19:56
User entered 'None (1)'	System	03 Sep 2020 21:19:56

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:30', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8d202023-13dd-45b0-a54b-48bf87373bf9' User entered 'No (N)'	System	03 Sep 2020 21:19:56
	System	03 Sep 2020 21:19:56

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:34', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8d202023-13dd-45b0-a54b-48bf87373bf9' User entered 'No (N)'	System	03 Sep 2020 21:19:56
	System	03 Sep 2020 21:19:56

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:43', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8d202023-13dd-45b0-a54b-48bf87373bf9'	System	03 Sep 2020 21:19:56
User entered 'None (1)'	System	03 Sep 2020 21:19:56

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:52', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '8d202023-13dd-45b0-a54b-48bf87373bf9' User entered '03 Sep 2020 17:19'	System	03 Sep 2020 21:19:56
	System	03 Sep 2020 21:19:56

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 3'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:16:57', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '902d941f-3cdd-4560-a044-3240f61a9b88'	System	05 Sep 2020 00:17:15
User entered 'None (1)'	System	05 Sep 2020 00:17:15

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '902d941f-3cdd-4560-a044-3240f61a9b88'	System	05 Sep 2020 00:17:15
User entered 'No (N)'	System	05 Sep 2020 00:17:15

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:05', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '902d941f-3cdd-4560-a044-3240f61a9b88'	System	05 Sep 2020 00:17:15
User entered 'No (N)'	System	05 Sep 2020 00:17:15

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:10', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '902d941f-3cdd-4560-a044-3240f61a9b88'	System	05 Sep 2020 00:17:15
User entered 'None (1)'	System	05 Sep 2020 00:17:15

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:14', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '902d941f-3cdd-4560-a044-3240f61a9b88'	System	05 Sep 2020 00:17:15
User entered '04 Sep 2020 20:17'	System	05 Sep 2020 00:17:15

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 4'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:31', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '2b4329d2-0450-495f-af53-1fbc165c1582'	System	06 Sep 2020 00:14:54
User entered 'None (1)'	System	06 Sep 2020 00:14:54

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:36', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '2b4329d2-0450-495f-af53-1fbc165c1582'	System	06 Sep 2020 00:14:54
User entered 'No (N)'	System	06 Sep 2020 00:14:54

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:39', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '2b4329d2-0450-495f-af53-1fbc165c1582'	System	06 Sep 2020 00:14:54
User entered 'No (N)'	System	06 Sep 2020 00:14:54

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:48', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '2b4329d2-0450-495f-af53-1fbc165c1582'	System	06 Sep 2020 00:14:54
User entered 'None (1)'	System	06 Sep 2020 00:14:54

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:52', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '2b4329d2-0450-495f-af53-1fbc165c1582'	System	06 Sep 2020 00:14:54
User entered '05 Sep 2020 20:14'	System	06 Sep 2020 00:14:54

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 5'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:28:54', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'fa56c64c-8925-4b98-adac-399f12cd0b8a'	System	07 Sep 2020 01:29:46
User entered 'None (1)'	System	07 Sep 2020 01:29:46

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:29:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'fa56c64c-8925-4b98-adac-399f12cd0b8a'	System	07 Sep 2020 01:29:46
User entered 'No (N)'	System	07 Sep 2020 01:29:46

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:29:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'fa56c64c-8925-4b98-adac-399f12cd0b8a'	System	07 Sep 2020 01:29:46
User entered 'No (N)'	System	07 Sep 2020 01:29:46

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:29:40', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'fa56c64c-8925-4b98-adac-399f12cd0b8a'	System	07 Sep 2020 01:29:46
User entered 'None (1)'	System	07 Sep 2020 01:29:46

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:29:43', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'fa56c64c-8925-4b98-adac-399f12cd0b8a'	System	07 Sep 2020 01:29:46
User entered '06 Sep 2020 21:29'	System	07 Sep 2020 01:29:46

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 6'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:28', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd4f49f11-118b-40dc-9656-4a68c4c3d04c' User entered 'None (1)'	System	08 Sep 2020 01:28:45
	System	08 Sep 2020 01:28:45

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:33', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd4f49f11-118b-40dc-9656-4a68c4c3d04c' User entered 'No (N)'	System	08 Sep 2020 01:28:45
	System	08 Sep 2020 01:28:45

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:36', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd4f49f11-118b-40dc-9656-4a68c4c3d04c' User entered 'No (N)'	System	08 Sep 2020 01:28:45
	System	08 Sep 2020 01:28:45

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:39', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd4f49f11-118b-40dc-9656-4a68c4c3d04c' User entered 'None (1)'	System	08 Sep 2020 01:28:45
	System	08 Sep 2020 01:28:45

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:42', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd4f49f11-118b-40dc-9656-4a68c4c3d04c' User entered '07 Sep 2020 21:28'	System	08 Sep 2020 01:28:45
	System	08 Sep 2020 01:28:45

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 7'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ae04e781-800d-46a4-8777-e0ea1d4cdf9'	System	09 Sep 2020 02:40:35
User entered 'None (1)'	System	09 Sep 2020 02:40:35

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:03', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ae04e781-800d-46a4-8777-e0ea1d4cdf9'	System	09 Sep 2020 02:40:35
User entered 'No (N)'	System	09 Sep 2020 02:40:35

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:06', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ae04e781-800d-46a4-8777-e0ea1d4cdf9'	System	09 Sep 2020 02:40:35
User entered 'No (N)'	System	09 Sep 2020 02:40:35

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:17', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ae04e781-800d-46a4-8777-e0ea1d4cdf9'	System	09 Sep 2020 02:40:35
User entered 'None (1)'	System	09 Sep 2020 02:40:35

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:32', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ae04e781-800d-46a4-8777-e0ea1d4cdf9'	System	09 Sep 2020 02:40:35
User entered '08 Sep 2020 22:40'	System	09 Sep 2020 02:40:35

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:20:57', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered 'None (0)'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:21:09', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered 'None (0)'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:21:14', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered 'None (0)'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:21:20', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered 'None (0)'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:21:35', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered 'None (0)'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:21:46', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered 'None (0)'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:21:58', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered 'No (N)'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T17:22:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '411e46b3-6737-491e-8240-28b92163401b' User entered '02 Sep 2020 17:22'	System	02 Sep 2020 21:22:14
	System	02 Sep 2020 21:22:14

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 17:04'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 19:34'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:31:55', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7' User entered 'None (0)'	System	03 Sep 2020 00:32:42
	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:32:02', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7' User entered 'None (0)'	System	03 Sep 2020 00:32:42
	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:32:07', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7' User entered 'None (0)'	System	03 Sep 2020 00:32:42
	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:32:16', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7' User entered 'None (0)'	System	03 Sep 2020 00:32:42
	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:32:24', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7' User entered 'None (0)'	System	03 Sep 2020 00:32:42
	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:32:28', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7' User entered 'None (0)'	System	03 Sep 2020 00:32:42
	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:32:34', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7'	System	03 Sep 2020 00:32:42
User entered 'No (N)'	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-02T20:32:37', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5b19015e-0877-48f1-847b-7e95d2f941d7' User entered '02 Sep 2020 20:32'	System	03 Sep 2020 00:32:42
	System	03 Sep 2020 00:32:42

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '02 Sep 2020 20:29'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 2'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:19:57', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1' User entered 'None (0)'	System	03 Sep 2020 21:20:41
	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:20:06', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1' User entered 'None (0)'	System	03 Sep 2020 21:20:41
	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:20:11', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1' User entered 'None (0)'	System	03 Sep 2020 21:20:41
	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:20:15', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1' User entered 'None (0)'	System	03 Sep 2020 21:20:41
	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:20:21', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1' User entered 'None (0)'	System	03 Sep 2020 21:20:41
	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:20:25', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1' User entered 'None (0)'	System	03 Sep 2020 21:20:41
	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:20:34', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1'	System	03 Sep 2020 21:20:41
User entered 'No (N)'	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-03T17:20:37', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '11548186-47f8-493b-90f1-6ed4b1fa4cb1' User entered '03 Sep 2020 17:20'	System	03 Sep 2020 21:20:41
	System	03 Sep 2020 21:20:41

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 3'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered 'None (0)'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:25', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered 'None (0)'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:33', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered 'None (0)'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:38', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered 'None (0)'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:43', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered 'None (0)'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:46', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered 'None (0)'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:50', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered 'No (N)'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-04T20:17:52', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4c4d4493-147e-4236-9491-3f894ddfed2'	System	05 Sep 2020 00:17:56
User entered '04 Sep 2020 20:17'	System	05 Sep 2020 00:17:56

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 4'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:14:58', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a'	System	06 Sep 2020 00:15:23
User entered 'None (0)'	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:15:01', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a'	System	06 Sep 2020 00:15:23
User entered 'None (0)'	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:15:04', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a'	System	06 Sep 2020 00:15:23
User entered 'None (0)'	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:15:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a' User entered 'None (0)'	System	06 Sep 2020 00:15:23
	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:15:11', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a'	System	06 Sep 2020 00:15:23
User entered 'None (0)'	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:15:13', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a'	System	06 Sep 2020 00:15:23
User entered 'None (0)'	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:15:17', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a'	System	06 Sep 2020 00:15:23
User entered 'No (N)'	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-05T20:15:20', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6c0064e7-b1f5-4d46-8003-56a4f6af0b6a'	System	06 Sep 2020 00:15:23
User entered '05 Sep 2020 20:15'	System	06 Sep 2020 00:15:23

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 5'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:29:51', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d' User entered 'None (0)'	System	07 Sep 2020 01:30:20
	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:29:54', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d' User entered 'None (0)'	System	07 Sep 2020 01:30:20
	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:30:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d' User entered 'None (0)'	System	07 Sep 2020 01:30:20
	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:30:02', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d'	System	07 Sep 2020 01:30:20
User entered 'None (0)'	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:30:04', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d' User entered 'None (0)'	System	07 Sep 2020 01:30:20
	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:30:11', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d'	System	07 Sep 2020 01:30:20
User entered 'None (0)'	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:30:15', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d'	System	07 Sep 2020 01:30:20
User entered 'No (N)'	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-06T21:30:17', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a17818cc-3546-4046-9037-a12c1afcdf4d' User entered '06 Sep 2020 21:30'	System	07 Sep 2020 01:30:20
	System	07 Sep 2020 01:30:20

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 6'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:50', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52' User entered 'None (0)'	System	08 Sep 2020 01:29:12
	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:53', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52' User entered 'None (0)'	System	08 Sep 2020 01:29:12
	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:55', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52' User entered 'None (0)'	System	08 Sep 2020 01:29:12
	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:57', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52' User entered 'None (0)'	System	08 Sep 2020 01:29:12
	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:28:59', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52' User entered 'None (0)'	System	08 Sep 2020 01:29:12
	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:29:01', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52'	System	08 Sep 2020 01:29:12
User entered 'None (0)'	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:29:07', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52'	System	08 Sep 2020 01:29:12
User entered 'No (N)'	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-07T21:29:09', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '62d4b490-5519-4f51-b5e4-a71405700b52'	System	08 Sep 2020 01:29:12
User entered '07 Sep 2020 21:29'	System	08 Sep 2020 01:29:12

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 7'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:39', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3'	System	09 Sep 2020 02:41:19
User entered 'None (0)'	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:48', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3'	System	09 Sep 2020 02:41:19
User entered 'None (0)'	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:51', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3'	System	09 Sep 2020 02:41:19
User entered 'None (0)'	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:40:56', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3'	System	09 Sep 2020 02:41:19
User entered 'None (0)'	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:41:05', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3'	System	09 Sep 2020 02:41:19
User entered 'None (0)'	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:41:09', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3' User entered 'None (0)'	System	09 Sep 2020 02:41:19
	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:41:14', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3' User entered 'No (N)'	System	09 Sep 2020 02:41:19
	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-08T22:41:17', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd65a33f7-2629-4c84-b19d-f125db7037e3'	System	09 Sep 2020 02:41:19
User entered '08 Sep 2020 22:41'	System	09 Sep 2020 02:41:19

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	09 Sep 2020 02:39:48
User entered 'Day 8'	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-10T05:46:46', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '275a874f-f8a4-4bbc-8ece-32f7edeb28d9'	System	10 Sep 2020 23:36:48
User entered 'No (N)'	System	10 Sep 2020 23:36:48

US3512199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-09-10T05:46:55', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '275a874f-f8a4-4bbc-8ece-32f7edeb28d9' User entered '10 Sep 2020 05:46'	System	10 Sep 2020 23:36:48
	System	10 Sep 2020 23:36:48

US3512199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 02:39:48

US3512199

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 02:39:48

US3512199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 15:27:47

US3512199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '10 Sep 2020'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 15:27:47
	(b) (4)	

US3512199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	14 Sep 2020 15:27:47

US3512199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 15:27:47

US3512199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Sep 2020 15:27:54

US3512199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	14 Sep 2020 15:27:54

US3512199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	18 Sep 2020 20:29:58

US3512199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '18 Sep 2020'	(b) (4) Sheldon Warren (b) (4)	18 Sep 2020 20:29:58
	(b) (4)	

US3512199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	18 Sep 2020 20:29:58
	(b) (4)	

US3512199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Sheldon Warren (b) (4)	18 Sep 2020 20:29:58
	(b) (4)	

US3512199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	18 Sep 2020 20:30:07

US3512199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	18 Sep 2020 20:30:07

US3512199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Sep 2020 21:35:25
	(b) (4)	

US3512199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '23 Sep 2020'	(b) (4) Sheldon Warren (b) (4)	23 Sep 2020 21:35:25
	(b) (4)	

US3512199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	23 Sep 2020 21:35:25
	(b) (4)	

US3512199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Sheldon Warren (b) (4)	23 Sep 2020 21:35:25
	(b) (4)	

US3512199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	23 Sep 2020 21:35:08

US3512199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	23 Sep 2020 21:35:08

US3512199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:40:57

US3512199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '30 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	30 Sep 2020 19:40:57
	(b) (4)	

US3512199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:40:57

US3512199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'VISIT2'	System	30 Sep 2020 19:40:57

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '30 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '15:06'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '30 Sep 2020 15:06'	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Per CDM: Temperature value is out of range per protocol. Please assess if NCS or CS and report AE if appropriate.' (Site from DM).	(b) (4)	19 Oct 2020 10:29:08
Query 'Per CDM: Temperature value is out of range per protocol. Please assess if NCS or CS and report AE if appropriate.' answered with 'Per monitor (b) (6) confirmed as is and no AE to be reported.' (Site from DM).	Allison Crain (b) (4)	16 Oct 2020 14:57:45
User opened query 'Per CDM: Temperature value is out of range per protocol. Please assess if NCS or CS and report AE if appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:56:11
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 03:55:00
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per monitor respond confirm as is' (Site from System).	Brenda Anderson (b) (4)	30 Sep 2020 19:42:14
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Sep 2020 19:41:51
User entered '96.7' F	Brenda Anderson (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '70'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'bpm'	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '18'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'breaths/min'	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '175'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '98'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:41:51

US3512199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:49:14

US3512199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '30 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	30 Sep 2020 19:49:14
	(b) (4)	

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Per CDM: Please complete the COVID-19 Assessment and AE page for the confirmed COVID-19.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete the COVID-19 Assessment and AE page for the confirmed COVID-19.' answered with 'pt asymptomatic at the baseline visit. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:16:07
User opened query 'Per CDM: Please complete the COVID-19 Assessment and AE page for the confirmed COVID-19.' (Site from DM).	Brenda Anderson (b) (4)	04 Nov 2020 14:52:27
User entered 'Confirmed COVID-19 (COVID)'	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 10:28:05
	Brenda Anderson (b) (4)	30 Sep 2020 19:50:21
	(b) (4)	

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:50:21

US3512199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:50:48

US3512199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '30 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	30 Sep 2020 19:50:48
	(b) (4)	

US3512199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '15:30'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:50:48

US3512199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '30 Sep 2020 15:30'	System	30 Sep 2020 19:50:48

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '30 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	30 Sep 2020 19:51:04
	(b) (4)	

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '15:12'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '30 Sep 2020 15:12'	System	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4)	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered empty.	System	30 Sep 2020 19:51:04

US3512199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	30 Sep 2020 19:51:08

US3512199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	30 Sep 2020 19:51:08

US3512199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 16:13:26
	(b) (4)	

US3512199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '7 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 16:13:26
	(b) (4)	

US3512199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 16:13:26
	(b) (4)	

US3512199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:13:26

US3512199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 16:13:33

US3512199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	07 Oct 2020 16:13:33

US3512199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	14 Oct 2020 21:04:37

US3512199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '14 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	14 Oct 2020 21:04:37
	(b) (4)	

US3512199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	14 Oct 2020 21:04:37

US3512199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Sheldon Warren (b) (4)	14 Oct 2020 21:04:37
	(b) (4)	

US3512199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	14 Oct 2020 21:04:42

US3512199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	14 Oct 2020 21:04:42

US3512199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	21 Oct 2020 16:03:50

US3512199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '21 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	21 Oct 2020 16:03:50
	(b) (4)	

US3512199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	21 Oct 2020 16:03:50

US3512199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Sheldon Warren (b) (4) (b) (4)	21 Oct 2020 16:03:50

US3512199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	21 Oct 2020 16:03:55

US3512199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	21 Oct 2020 16:03:55

US3512199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:35:42

US3512199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '30 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:35:42

US3512199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	04 Nov 2020 14:35:42

US3512199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'VISIT3'	System	04 Nov 2020 14:35:42

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '30 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '14:35'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '30 Oct 2020 14:35'	System	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '98.6' F	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '75'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'bpm'	System	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '18'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'breaths/min'	System	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '154'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '93'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered 'mmHg'	System	04 Nov 2020 14:37:17

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52

US3512199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52

US3512199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:27

US3512199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:27

US3512199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:51

US3512199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '30 Oct 2020'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:37:51

US3512199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '14:43'	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:37:51

US3512199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '30 Oct 2020 14:43'	System	04 Nov 2020 14:37:51

US3512199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:37:58

US3512199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	04 Nov 2020 14:37:58

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 64'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-02T07:12:12', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '914a9772-0af3-43d1-8a27-8484ee3ec9c4'	System	02 Nov 2020 12:12:33
User entered 'No (N)'	System	02 Nov 2020 12:12:33

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-02T07:12:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '914a9772-0af3-43d1-8a27-8484ee3ec9c4'	System	02 Nov 2020 12:12:33
User entered 'No (N)'	System	02 Nov 2020 12:12:33

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-02T07:12:28', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '914a9772-0af3-43d1-8a27-8484ee3ec9c4' User entered '02 Nov 2020 07:12:28'	System	02 Nov 2020 12:12:33
	System	02 Nov 2020 12:12:33

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 71'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-09T07:56:13', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c24e7066-c849-4879-a069-eb79ac9e8e49'	System	09 Nov 2020 12:56:32
User entered 'No (N)'	System	09 Nov 2020 12:56:32

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-09T07:56:21', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c24e7066-c849-4879-a069-eb79ac9e8e49'	System	09 Nov 2020 12:56:32
User entered 'No (N)'	System	09 Nov 2020 12:56:32

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-09T07:56:27', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c24e7066-c849-4879-a069-eb79ac9e8e49' User entered '09 Nov 2020 07:56:27'	System	09 Nov 2020 12:56:32
	System	09 Nov 2020 12:56:32

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered 'Day 78'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-16T10:32:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '663062b8-43cc-4443-b217-f9c7fe1a1951'	System	16 Nov 2020 15:32:39
User entered 'No (N)'	System	16 Nov 2020 15:32:39

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-16T10:32:31', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '663062b8-43cc-4443-b217-f9c7fe1a1951'	System	16 Nov 2020 15:32:39
User entered 'No (N)'	System	16 Nov 2020 15:32:39

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-16T10:32:36', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '663062b8-43cc-4443-b217-f9c7fe1a1951' User entered '16 Nov 2020 10:32:36'	System	16 Nov 2020 15:32:39
	System	16 Nov 2020 15:32:39

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 21:04:02

US3512199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:25:51
Data entry locked.	System	02 Sep 2020 21:04:02
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 21:04:02

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-30T08:34:16', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '3908762e-05f6-4aae-9197-3d087a5c4b9e'	System	30 Nov 2020 13:35:00
User entered 'No (N)'	System	30 Nov 2020 13:35:00

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-30T08:34:20', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '3908762e-05f6-4aae-9197-3d087a5c4b9e'	System	30 Nov 2020 13:35:00
User entered 'No (N)'	System	30 Nov 2020 13:35:00

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-11-30T08:34:27', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '3908762e-05f6-4aae-9197-3d087a5c4b9e' User entered '30 Nov 2020 08:34:27'	System	30 Nov 2020 13:35:00
	System	30 Nov 2020 13:35:00

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-06T12:45:33', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7de258a5-0ab3-4bd2-9341-21059e5125ef'	System	06 Dec 2020 17:46:34
User entered 'No (N)'	System	06 Dec 2020 17:46:34

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-06T12:46:14', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7de258a5-0ab3-4bd2-9341-21059e5125ef'	System	06 Dec 2020 17:46:34
User entered 'Yes (Y)'	System	06 Dec 2020 17:46:34

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Please 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-06T12:46:17', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7de258a5-0ab3-4bd2-9341-21059e5125ef'	System	06 Dec 2020 17:46:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 17:46:34

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-06T12:46:23', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7de258a5-0ab3-4bd2-9341-21059e5125ef' User entered '06 Dec 2020 12:46:23'	System	06 Dec 2020 17:46:34
	System	06 Dec 2020 17:46:34

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-11T07:20:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '45f4c47e-4931-409d-a242-5f53ad7a8285'	System	11 Dec 2020 12:20:21
User entered 'No (N)'	System	11 Dec 2020 12:20:21

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-11T07:20:12', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '45f4c47e-4931-409d-a242-5f53ad7a8285'	System	11 Dec 2020 12:20:21
User entered 'No (N)'	System	11 Dec 2020 12:20:21

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-11T07:20:17', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '45f4c47e-4931-409d-a242-5f53ad7a8285'	System	11 Dec 2020 12:20:21
User entered '11 Dec 2020 07:20:17'	System	11 Dec 2020 12:20:21

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-21T17:59:38', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '39e149dc-cde0-4676-8bc4-f64c8850c534'	System	21 Dec 2020 22:59:52
User entered 'No (N)'	System	21 Dec 2020 22:59:52

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-21T17:59:44', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '39e149dc-cde0-4676-8bc4-f64c8850c534'	System	21 Dec 2020 22:59:52
User entered 'No (N)'	System	21 Dec 2020 22:59:52

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-21T17:59:50', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '39e149dc-cde0-4676-8bc4-f64c8850c534'	System	21 Dec 2020 22:59:52
User entered '21 Dec 2020 17:59:50'	System	21 Dec 2020 22:59:52

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-27T12:12:04', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4762c6d3-2ccf-4b55-9b2a-8071aa687d5f' User entered 'No (N)'	System	27 Dec 2020 17:37:38
	System	27 Dec 2020 17:37:38

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-27T12:37:31', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4762c6d3-2ccf-4b55-9b2a-8071aa687d5f' User entered 'No (N)'	System	27 Dec 2020 17:37:38
	System	27 Dec 2020 17:37:38

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2020-12-27T12:37:36', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '4762c6d3-2ccf-4b55-9b2a-8071aa687d5f' User entered '27 Dec 2020 12:37:36'	System	27 Dec 2020 17:37:38
	System	27 Dec 2020 17:37:38

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-05T10:35:01', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7b6e9a01-1a89-43bf-a6d8-fd9e96e0678b'	System	05 Jan 2021 15:35:16
User entered 'No (N)'	System	05 Jan 2021 15:35:16

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-05T10:35:07', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7b6e9a01-1a89-43bf-a6d8-fd9e96e0678b'	System	05 Jan 2021 15:35:16
User entered 'No (N)'	System	05 Jan 2021 15:35:16

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-05T10:35:12', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '7b6e9a01-1a89-43bf-a6d8-fd9e96e0678b' User entered '05 Jan 2021 10:35:12'	System	05 Jan 2021 15:35:16
	System	05 Jan 2021 15:35:16

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-11T17:59:49', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd999af5e-1000-4131-8ac9-067d2866c4d9'	System	11 Jan 2021 23:00:02
User entered 'No (N)'	System	11 Jan 2021 23:00:02

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-11T17:59:54', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd999af5e-1000-4131-8ac9-067d2866c4d9'	System	11 Jan 2021 23:00:02
User entered 'No (N)'	System	11 Jan 2021 23:00:02

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-11T17:59:58', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd999af5e-1000-4131-8ac9-067d2866c4d9' User entered '11 Jan 2021 17:59:58'	System	11 Jan 2021 23:00:02
	System	11 Jan 2021 23:00:02

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-18T08:12:51', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '0ee68b22-c62b-4e55-b636-8e2463503fef'	System	18 Jan 2021 13:13:04
User entered 'No (N)'	System	18 Jan 2021 13:13:04

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-18T08:12:55', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '0ee68b22-c62b-4e55-b636-8e2463503fef'	System	18 Jan 2021 13:13:04
User entered 'No (N)'	System	18 Jan 2021 13:13:04

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-18T08:12:59', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '0ee68b22-c62b-4e55-b636-8e2463503fef' User entered '18 Jan 2021 08:12:59'	System	18 Jan 2021 13:13:04
	System	18 Jan 2021 13:13:04

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-24T12:01:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '477ae62a-223f-44bd-82b2-41fb71bee2a0' User entered 'No (N)'	System	24 Jan 2021 17:03:31
	System	24 Jan 2021 17:03:31

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-24T12:01:15', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '477ae62a-223f-44bd-82b2-41fb71bee2a0'	System	24 Jan 2021 17:03:31
User entered 'Yes (Y)'	System	24 Jan 2021 17:03:31

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Please 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-24T12:01:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '477ae62a-223f-44bd-82b2-41fb71bee2a0'	System	24 Jan 2021 17:03:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 17:03:31

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-24T12:01:33', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '477ae62a-223f-44bd-82b2-41fb71bee2a0' User entered '24 Jan 2021 12:01:33'	System	24 Jan 2021 17:03:31
	System	24 Jan 2021 17:03:31

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-31T12:00:28', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'cd0fd573-1300-488c-a35b-2980ab311227'	System	31 Jan 2021 17:01:41
User entered 'No (N)'	System	31 Jan 2021 17:01:41

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-31T12:00:35', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'cd0fd573-1300-488c-a35b-2980ab311227'	System	31 Jan 2021 17:01:41
User entered 'No (N)'	System	31 Jan 2021 17:01:41

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-01-31T12:00:39', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'cd0fd573-1300-488c-a35b-2980ab311227'	System	31 Jan 2021 17:01:41
User entered '31 Jan 2021 12:00:39'	System	31 Jan 2021 17:01:41

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-05T09:04:01', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '29bc6e8b-425b-4f49-8ff3-5f5ea9f8471a'	System	05 Feb 2021 14:04:14
User entered 'No (N)'	System	05 Feb 2021 14:04:14

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-05T09:04:05', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '29bc6e8b-425b-4f49-8ff3-5f5ea9f8471a'	System	05 Feb 2021 14:04:14
User entered 'No (N)'	System	05 Feb 2021 14:04:14

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-05T09:04:09', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '29bc6e8b-425b-4f49-8ff3-5f5ea9f8471a' User entered '05 Feb 2021 09:04:09'	System	05 Feb 2021 14:04:14
	System	05 Feb 2021 14:04:14

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-14T12:00:39', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '64d230d1-78ef-430b-bec3-f9a5e6e60825'	System	14 Feb 2021 17:04:50
User entered 'No (N)'	System	14 Feb 2021 17:04:50

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-14T12:01:07', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '64d230d1-78ef-430b-bec3-f9a5e6e60825'	System	14 Feb 2021 17:04:50
User entered 'No (N)'	System	14 Feb 2021 17:04:50

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-14T12:01:12', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '64d230d1-78ef-430b-bec3-f9a5e6e60825' User entered '14 Feb 2021 12:01:12'	System	14 Feb 2021 17:04:50
	System	14 Feb 2021 17:04:50

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-19T08:54:19', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a1457c59-e52c-40ba-b4c2-2702b79f5227'	System	19 Feb 2021 13:54:36
User entered 'No (N)'	System	19 Feb 2021 13:54:36

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-19T08:54:24', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a1457c59-e52c-40ba-b4c2-2702b79f5227'	System	19 Feb 2021 13:54:36
User entered 'No (N)'	System	19 Feb 2021 13:54:36

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-19T08:54:28', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'a1457c59-e52c-40ba-b4c2-2702b79f5227'	System	19 Feb 2021 13:54:36
User entered '19 Feb 2021 08:54:28'	System	19 Feb 2021 13:54:36

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-26T08:29:40', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd36da675-1c28-4041-866b-24ba16698468'	System	26 Feb 2021 13:29:56
User entered 'No (N)'	System	26 Feb 2021 13:29:56

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-26T08:29:48', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd36da675-1c28-4041-866b-24ba16698468'	System	26 Feb 2021 13:29:56
User entered 'No (N)'	System	26 Feb 2021 13:29:56

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-02-26T08:29:52', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd36da675-1c28-4041-866b-24ba16698468'	System	26 Feb 2021 13:29:56
User entered '26 Feb 2021 08:29:52'	System	26 Feb 2021 13:29:56

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-05T08:36:37', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5c69f2bf-62f1-4a16-963a-bd2530964e63'	System	05 Mar 2021 13:36:49
User entered 'No (N)'	System	05 Mar 2021 13:36:49

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-05T08:36:40', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5c69f2bf-62f1-4a16-963a-bd2530964e63'	System	05 Mar 2021 13:36:49
User entered 'No (N)'	System	05 Mar 2021 13:36:49

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-05T08:36:45', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '5c69f2bf-62f1-4a16-963a-bd2530964e63' User entered '05 Mar 2021 08:36:45'	System	05 Mar 2021 13:36:49
	System	05 Mar 2021 13:36:49

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-12T10:53:39-05:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '00cd1743-80df-48ca-ba68-597ba5593dc8'	System	12 Mar 2021 15:53:55
User entered 'No (N)'	System	12 Mar 2021 15:53:55

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-12T10:53:44-05:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '00cd1743-80df-48ca-ba68-597ba5593dc8'	System	12 Mar 2021 15:53:55
User entered 'No (N)'	System	12 Mar 2021 15:53:55

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-12T10:53:50-05:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '00cd1743-80df-48ca-ba68-597ba5593dc8'	System	12 Mar 2021 15:53:55
User entered '12 Mar 2021 10:53:50'	System	12 Mar 2021 15:53:55

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-19T08:15:51-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '69c6d7a9-84b8-4aec-8085-cb390b65d2ea'	System	19 Mar 2021 12:16:06
User entered 'No (N)'	System	19 Mar 2021 12:16:06

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-19T08:15:57-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '69c6d7a9-84b8-4aec-8085-cb390b65d2ea'	System	19 Mar 2021 12:16:06
User entered 'No (N)'	System	19 Mar 2021 12:16:06

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-19T08:16:01-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '69c6d7a9-84b8-4aec-8085-cb390b65d2ea' User entered '19 Mar 2021 08:16:01'	System	19 Mar 2021 12:16:06
	System	19 Mar 2021 12:16:06

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-29T12:51:51-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '9bd89e14-7d0e-4c1b-bd1b-27efc61a1c4f'	System	29 Mar 2021 16:52:05
User entered 'No (N)'	System	29 Mar 2021 16:52:05

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-29T12:51:56-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '9bd89e14-7d0e-4c1b-bd1b-27efc61a1c4f'	System	29 Mar 2021 16:52:05
User entered 'No (N)'	System	29 Mar 2021 16:52:05

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-29T12:52:00-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '9bd89e14-7d0e-4c1b-bd1b-27efc61a1c4f'	System	29 Mar 2021 16:52:05
User entered '29 Mar 2021 12:52:00'	System	29 Mar 2021 16:52:05

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-02T07:42:06-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ccb8c440-52f6-4f44-aa3a-dc659c07b449'	System	02 Apr 2021 11:42:25
User entered 'No (N)'	System	02 Apr 2021 11:42:25

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-02T07:42:13-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ccb8c440-52f6-4f44-aa3a-dc659c07b449'	System	02 Apr 2021 11:42:25
User entered 'No (N)'	System	02 Apr 2021 11:42:25

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-02T07:42:21-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'ccb8c440-52f6-4f44-aa3a-dc659c07b449'	System	02 Apr 2021 11:42:25
User entered '02 Apr 2021 07:42:21'	System	02 Apr 2021 11:42:25

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-09T12:02:45-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd9ece674-3c64-4c79-8305-3a2e827b6aeb'	System	09 Apr 2021 16:08:15
User entered 'No (N)'	System	09 Apr 2021 16:08:15

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-09T12:02:56-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd9ece674-3c64-4c79-8305-3a2e827b6aeb'	System	09 Apr 2021 16:08:15
User entered 'No (N)'	System	09 Apr 2021 16:08:15

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-09T12:03:01-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'd9ece674-3c64-4c79-8305-3a2e827b6aeb' User entered '09 Apr 2021 12:03:01'	System	09 Apr 2021 16:08:15
	System	09 Apr 2021 16:08:15

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-18T12:00:48-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c02a5cd7-4661-4425-b598-2e08671a7c58'	System	18 Apr 2021 16:01:58
User entered 'No (N)'	System	18 Apr 2021 16:01:58

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-18T12:00:50-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c02a5cd7-4661-4425-b598-2e08671a7c58'	System	18 Apr 2021 16:01:58
User entered 'No (N)'	System	18 Apr 2021 16:01:58

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-18T12:00:54-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'c02a5cd7-4661-4425-b598-2e08671a7c58'	System	18 Apr 2021 16:01:58
User entered '18 Apr 2021 12:00:54'	System	18 Apr 2021 16:01:58

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-23T16:18:13-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6ed4c60c-7674-443a-ab37-59a60cd70ecb'	System	23 Apr 2021 20:18:25
User entered 'No (N)'	System	23 Apr 2021 20:18:25

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-23T16:18:19-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6ed4c60c-7674-443a-ab37-59a60cd70ecb'	System	23 Apr 2021 20:18:25
User entered 'No (N)'	System	23 Apr 2021 20:18:25

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-04-23T16:18:23-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '6ed4c60c-7674-443a-ab37-59a60cd70ecb'	System	23 Apr 2021 20:18:25
User entered '23 Apr 2021 16:18:23'	System	23 Apr 2021 20:18:25

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-05-03T10:58:29-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'b0e25dfd-fb6e-4ab4-932f-bd5077de4cd9'	System	03 May 2021 14:58:45
User entered 'No (N)'	System	03 May 2021 14:58:45

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

Have you been exposed to someone with 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 (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-05-03T10:58:33-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'b0e25dfd-fb6e-4ab4-932f-bd5077de4cd9'	System	03 May 2021 14:58:45
User entered 'No (N)'	System	03 May 2021 14:58:45

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-05-03T10:58:37-04:00', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: 'b0e25dfd-fb6e-4ab4-932f-bd5077de4cd9'	System	03 May 2021 14:58:45
User entered '03 May 2021 10:58:37'	System	03 May 2021 14:58:45

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:54:39

US3512199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:54:39
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:54:39

US3512199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:49

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 19:38:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-05T08:36:56', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '45546b9d-f3f9-45d1-b41b-2954f20aef45'	System	05 Mar 2021 13:37:10
User entered 'No (N)'	System	05 Mar 2021 13:37:10

US3512199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:38:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F54B5BD1-BBBF-43F0-BF00-EBDF42EE9961)', Time: '2021-03-05T08:37:08', User OID: 'PatientReportedOutcome (US3512199)', ODM File OID: '45546b9d-f3f9-45d1-b41b-2954f20aef45'	System	05 Mar 2021 13:37:10
User entered '05 Mar 2021 08:37:08'	System	05 Mar 2021 13:37:10

US3512199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 21:57:44
	(b) (4)	

US3512199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '27 Nov 2020'	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 21:57:44
	(b) (4)	

US3512199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 21:57:44

US3512199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 21:57:44
	(b) (4)	

US3512199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	27 Nov 2020 21:57:49
	(b) (4)	

US3512199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:59:52
User entered '1'	System	27 Nov 2020 21:57:49

US3512199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	31 Dec 2020 16:44:23

US3512199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '31 Dec 2020'	(b) (4) Sheldon Warren (b) (4)	31 Dec 2020 16:44:23
	(b) (4)	

US3512199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	31 Dec 2020 16:44:23

US3512199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Sheldon Warren (b) (4)	31 Dec 2020 16:44:23
	(b) (4)	

US3512199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	31 Dec 2020 16:44:11

US3512199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User entered 'I'	System	31 Dec 2020 16:44:11

US3512199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 12-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	22 Feb 2021 12:33:39
' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 12-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:11:59
' answered with 'Added to EDC' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 12-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	19 Feb 2021 05:42:02
' (Site from DM). User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	28 Jan 2021 22:31:17

US3512199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '28 Jan 2021'	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 22:31:17
	(b) (4)	

US3512199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 22:31:17

US3512199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 22:31:17
	(b) (4)	

US3512199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	28 Jan 2021 22:31:09

US3512199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User entered '1'	System	28 Jan 2021 22:31:09

US3512199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	24 Feb 2021 19:24:06

US3512199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered '24 Feb 2021'	(b) (4) Sheldon Warren (b) (4)	24 Feb 2021 19:24:06
	(b) (4)	

US3512199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	24 Feb 2021 19:24:06

US3512199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered empty.	(b) (4) Sheldon Warren (b) (4)	24 Feb 2021 19:24:06
	(b) (4)	

US3512199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	24 Feb 2021 19:24:11

US3512199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:55:44
User entered '1'	System	24 Feb 2021 19:24:11

US3512199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:37

US3512199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:37

US3512199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:37

US3512199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	09 Apr 2021 17:28:37

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:46

US3512199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:30:21

US3512199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:30:21

US3512199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:31:02

US3512199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:31:02

US3512199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered '13:12'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:31:02

US3512199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 13:12'	System	09 Apr 2021 17:31:02

US3512199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:31:13

US3512199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 17:31:13

US3512199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:42
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Apr 2021 19:57:11
	(b) (4)	

US3512199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:42
	(b) (4)	
User entered '26 Apr 2021'	Sheldon Warren (b) (4)	26 Apr 2021 19:57:11
	(b) (4)	

US3512199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	26 Apr 2021 19:57:11
	(b) (4)	

US3512199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:42
	(b) (4)	
User entered empty.	Sheldon Warren (b) (4)	26 Apr 2021 19:57:11
	(b) (4)	

US3512199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:42
	(b) (4)	
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	26 Apr 2021 19:57:02
	(b) (4)	

US3512199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 19:57:02

US3512199

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:49

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User closed query 'Please provide source for this covid contact and supporting documents to CRA.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 06:46:55
User closed query 'Please provide source for this covid contact and supporting documents to CRA.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:58:26
Query 'Data is required. Please complete.' answered with 'per edc guidelines not needed' (Site from System).	Brenda Anderson (b) (4)	04 Feb 2021 16:53:16
Query 'Please provide source for this covid contact and supporting documents to CRA.' answered with 'per edc guidelines not needed' (Site from CRA).	Brenda Anderson (b) (4)	04 Feb 2021 16:53:13
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 16:52:55
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 16:52:55
User opened query 'Please provide source for this covid contact and supporting documents to CRA.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 14:13:00
User entered '10 Sep 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	12 Nov 2020 15:55:11
User entered '11 Sep 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Nov 2020 14:58:00
User entered '14 Sep 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Nov 2020 14:56:12
User entered '11 Sep 2020'	Brenda Anderson (b) (4)	04 Nov 2020 14:53:55

US3512199

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:49

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:14
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Feb 2021 16:52:55
User closed query 'Per CDM: Please complete page.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:10:53
Query 'Per CDM: Please complete page.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	12 Nov 2020 15:55:18
User entered '17:29' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	12 Nov 2020 15:55:11
User opened query 'Per CDM: Please complete page.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:17:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 05:17:24
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:59:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 14:58:44
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:58:44
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 14:56:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 14:56:12
User entered '11:40' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:56:12
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 14:53:55
User entered empty.	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:53:55

US3512199

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:49

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:14
User entered empty.	System	04 Feb 2021 16:52:55
User entered '10 Sep 2020 17:29'	System	12 Nov 2020 15:55:11
User entered empty.	System	04 Nov 2020 14:58:44
User entered '11 Sep 2020 11:40'	System	04 Nov 2020 14:58:00
User entered '14 Sep 2020 11:40'	System	04 Nov 2020 14:56:12
User entered empty.	System	04 Nov 2020 14:53:55

US3512199

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:49

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'per edc guidelines not needed' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 06:47:06
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	04 Feb 2021 16:53:20
Query 'Data is required. Please complete.' answered with 'per edc guidelines not needed' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 16:52:55
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 16:52:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 15:55:11
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	System	12 Nov 2020 15:55:11
User opened query 'Data is required. Please complete.' (Site from System).	Allison Crain (b) (4)	12 Nov 2020 15:55:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	04 Nov 2020 15:17:29
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	04 Nov 2020 15:17:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	04 Nov 2020 14:56:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Brenda Anderson (b) (4)	04 Nov 2020 14:53:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	

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Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:49

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:14
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'per edc guidelines not needed' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 06:47:09
Query 'Data is required. Please complete.' answered with 'per edc guidelines not needed' (Site from System).	Brenda Anderson (b) (4)	04 Feb 2021 16:53:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 16:52:55
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	04 Feb 2021 16:52:55
User entered 'No (N)'	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	04 Nov 2020 14:53:55
	(b) (4)	

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Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:49:49

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:10
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'per edc guidelines not needed' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 06:40:24
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	04 Feb 2021 16:53:35
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	04 Nov 2020 14:56:47
	(b) (4)	

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:04

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User entered '12 Feb 2021'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:04

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User entered 'Clinic (Clinic)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:04

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'UNBLND_DECIDE'	System	19 Feb 2021 14:08:04

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered '12 Feb 2021'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:50:36
User entered '0' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:34:30

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:50:36
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:34:30

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered '12 Feb 2021'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Placebo (Placebo)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Placebo (Placebo)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Not Administered (NA)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '1'	System	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:49:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '1'	System	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '71' in	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '192.6' lb	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '26.91841'	System	19 Feb 2021 14:09:08
DataPoint set to visible.	System	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '71' in	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '192.6' lb	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '26.91841'	System	19 Feb 2021 14:09:08
DataPoint set to visible.	System	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 14:09:43
User entered '12 Feb 2021' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:43
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Feb 2021 14:09:08
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 14:09:43
User entered '14:43' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Feb 2021 14:09:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:08
User entered empty.	System	19 Feb 2021 14:09:08
	Allison Crain (b) (4)	19 Feb 2021 14:09:08
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Feb 2021 14:43'	System	19 Feb 2021 14:09:43
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 14:09:43
User entered '98.9' F reason for change: Data Entry Error	Allison Crain (b) (4)	19 Feb 2021 14:09:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:08
User entered empty.	Allison Crain (b) (4)	19 Feb 2021 14:09:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:43
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User entered empty.	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 14:09:43
User entered '74' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Feb 2021 14:09:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:08
User entered empty.	System	19 Feb 2021 14:09:08
	Allison Crain (b) (4)	19 Feb 2021 14:09:08
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'bpm'	System	19 Feb 2021 14:09:43
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 14:09:43
User entered '16' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Feb 2021 14:09:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:08
User entered empty.	System	19 Feb 2021 14:09:08
	Allison Crain (b) (4)	19 Feb 2021 14:09:08
	(b) (4)	

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'breaths/min'	System	19 Feb 2021 14:09:43
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 14:09:43
User entered '141' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Feb 2021 14:09:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:08
User entered empty.	System	19 Feb 2021 14:09:08
	Allison Crain (b) (4)	19 Feb 2021 14:09:08
	(b) (4)	

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	19 Feb 2021 14:09:43
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Feb 2021 14:09:43
User entered '90' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Feb 2021 14:09:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 14:09:08
User entered empty.	System	19 Feb 2021 14:09:08
	Allison Crain (b) (4)	19 Feb 2021 14:09:08
	(b) (4)	

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	19 Feb 2021 14:09:43
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '71' in	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '192.6' lb	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '26.91841'	System	19 Feb 2021 14:09:08
DataPoint set to visible.	System	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 14:10:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 14:10:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4)	19 Feb 2021 14:10:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 14:09:08
User entered empty.	System	19 Feb 2021 14:09:08
	Allison Crain (b) (4)	19 Feb 2021 14:09:08
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '12 Feb 2021' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '16:37' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Feb 2021 16:37'	System	19 Feb 2021 14:10:27
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4)	19 Feb 2021 14:09:08
	(b) (4)	

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:39
User entered empty.	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '72' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'bpm'	System	19 Feb 2021 14:10:27
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '16' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'breaths/min'	System	19 Feb 2021 14:10:27
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '131' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	19 Feb 2021 14:10:27
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:39
User entered '92' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:27
User entered empty.	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	19 Feb 2021 14:10:27
User entered empty.	System	19 Feb 2021 14:09:08

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:38
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:37

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered '12 Feb 2021'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:10:37
	(b) (4)	

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:38
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered empty.	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered empty.	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mRNA-1273'	System	19 Feb 2021 14:10:55
DataPoint set to visible.	System	19 Feb 2021 14:08:43

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered '12 Feb 2021'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:38
User entered '16:06'	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Feb 2021 16:06'	System	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'ONCE'	System	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 14:10:55

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Feb 2021 21:25:38
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	19 Feb 2021 14:11:14

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 12Feb21. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 12Feb21. Please provide accession number and tracking or clarify. Thank you.' answered with 'site has report stating lab received specimens. REQ ID 1F6561241179 tracking 949321509529' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:01:16
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 visit on 12Feb21. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User signature succeeded.	Brenda Anderson (b) (4) (b) (4)	04 Mar 2021 14:04:16
User entered '12 Feb 2021'	(b) (4), (b) (6) Michael Koren (b) (4) Allison Crain (b) (4) (b) (4)	25 Feb 2021 15:58:24 19 Feb 2021 21:25:38 19 Feb 2021 14:11:14

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered '14:20'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:11:14

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Feb 2021 14:20'	System	19 Feb 2021 14:11:14

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:11:27

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered '12 Feb 2021'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:11:27

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered '14:17'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:11:27

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:49

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Feb 2021 14:17'	System	19 Feb 2021 14:11:27

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Feb 2021 21:25:38
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	19 Feb 2021 14:11:32

US3512199

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '1'	System	19 Feb 2021 14:11:32

US3512199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	26 Feb 2021 20:01:08
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	22 Feb 2021 18:04:30

US3512199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered '22 Feb 2021'	(b) (4) Sheldon Warren (b) (4)	22 Feb 2021 18:04:30
	(b) (4)	

US3512199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	22 Feb 2021 18:04:30

US3512199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered empty.	(b) (4) Sheldon Warren (b) (4)	22 Feb 2021 18:04:30

US3512199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Feb 2021 20:01:08
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	22 Feb 2021 18:04:36

US3512199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '1'	System	22 Feb 2021 18:04:36

US3512199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '1'	System	22 Feb 2021 18:04:36
DataPoint set to visible.	System	22 Feb 2021 18:04:36

US3512199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:35:42

US3512199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '12 Mar 2021'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:35:42

US3512199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Clinic (Clinic)'	(b) (4) Brenda Anderson (b) (4)	17 Mar 2021 12:35:42

US3512199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'OLD29'	System	17 Mar 2021 12:35:42

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '12 Mar 2021'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '14:13'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Mar 2021 14:13'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '98.1' F	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '79'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'bpm'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '16'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'breaths/min'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '126'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '71'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '12 Mar 2021'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '15:15'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Mar 2021 15:15'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '98.6' F	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '68'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'bpm'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '14'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'breaths/min'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '146'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '90'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mmHg'	System	17 Mar 2021 12:37:31

US3512199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:45

US3512199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Mar 2021 12:38:02
User entered '12 Mar 2021' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:38:02
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Mar 2021 12:37:45
User entered '16 Mar 2021'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:37:45

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'mRNA-1273'	System	17 Mar 2021 12:38:33
DataPoint set to visible.	System	22 Feb 2021 18:04:36

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '12 Mar 2021'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered '14:44'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '12 Mar 2021 14:44'	System	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered 'Left Arm (LEFT ARM)'	Brenda Anderson (b) (4) (b) (4)	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'ONCE'	System	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'INTRAMUSCULAR'	System	17 Mar 2021 12:38:33

US3512199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4)	17 Mar 2021 12:38:38

US3512199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered '1'	System	17 Mar 2021 12:38:38

US3512199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:55
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	22 Mar 2021 21:02:55

US3512199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:55
User entered '19 Mar 2021'	(b) (4) Sheldon Warren (b) (4)	22 Mar 2021 21:02:55

US3512199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	22 Mar 2021 21:02:55

US3512199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:55
User entered empty.	(b) (4) Sheldon Warren (b) (4)	22 Mar 2021 21:02:55
	(b) (4)	

US3512199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User signature succeeded.	Michael Koren (b) (4)	26 Mar 2021 14:25:55
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	22 Mar 2021 21:02:44

US3512199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:07
User entered 'I'	System	22 Mar 2021 21:02:44

US3512199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:01

US3512199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:01

US3512199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:01

US3512199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	09 Apr 2021 17:28:01

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:28:08

US3512199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:15

US3512199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:15

US3512199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:27

US3512199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:27

US3512199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:44:44
User entered '13:12'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:28:27

US3512199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Apr 2021 13:12'	System	09 Apr 2021 17:28:27

US3512199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:49:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:17
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:30:08

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of RIGHT SHOULDER PAIN. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 09:48:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder soreness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 19:32:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 19:32:42
Data point term sent to Coder	System	08 Jan 2021 17:09:53
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of RIGHT SHOULDER PAIN. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'AGREE, CHANGED' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	08 Jan 2021 17:09:43
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	08 Jan 2021 17:09:28
User entered 'WORSENING RIGHT SHOULDER SORENESS SECONDARY TO YARD WORK' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	08 Jan 2021 17:09:28
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of RIGHT SHOULDER PAIN. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 00:54:43

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder soreness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:35:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:35:33
Data point term sent to Coder	System	12 Nov 2020 14:32:48
User entered 'RIGHT SHOULDER SORENESS SECONDARY TO YARD WORK'	Allison Crain (b) (4) (b) (4)	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '8 Sep 2020'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '8 Sep 2020'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 05:45:11
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. answered with 'Graded mild per Sub-I' (Site from DM).	Allison Crain (b) (4) (b) (4)	16 Mar 2021 15:50:30
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 03:07:21
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 15:51:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 15:51:57
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	12 Nov 2020 15:51:57
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 14:31:52
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	19 Mar 2021 20:44:28
User entered empty.	Allison Crain (b) (4) (b) (4)	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '0'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'I'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Allison Crain (b) (4)	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	12 Nov 2020 14:31:52
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 14:31:52

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Dec 2020 21:33:21
Data point term sent to Coder	System	21 Dec 2020 15:37:27
User entered 'asymptomatic covid-19 infection'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'answered, no asymptomatic COVID-19' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:10:43
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	21 Dec 2020 19:58:32
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety). User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4), (b) (6) Brenda Anderson (b) (4) (b) (4)	21 Dec 2020 19:58:11 21 Dec 2020 18:56:18 21 Dec 2020 15:36:35

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '2 Sep 2020'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Dec 2020 15:38:40
User entered '16:00' reason for change: Data Entry Error	Brenda Anderson (b) (4)	21 Dec 2020 15:38:40
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Dec 2020 15:36:35
User entered empty.	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Sep 2020 16:00'	System	21 Dec 2020 15:38:40
User entered empty.	System	21 Dec 2020 15:36:35

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '12 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:53:04
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Brenda Anderson (b) (4) (b) (4)	21 Dec 2020 15:42:21
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Dec 2020 15:36:35
User entered empty.	Brenda Anderson (b) (4) (b) (4)	21 Dec 2020 15:36:35

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 15:36:35

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Not Related (NOT RELATED)'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 09:51:48
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Withdrawn due to Asymptomatic SARS CoV2 infection at visit 1. This is recorded in Dosing Discontinuation, but the AE is also recorded. Please advise if you want this changed to withdrawn due to AE.' (Site from System).	Allison Crain (b) (4) (b) (4)	21 Dec 2020 16:13:31
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	21 Dec 2020 15:36:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Brenda Anderson (b) (4) (b) (4)	21 Dec 2020 15:36:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '1'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered '0'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:44:28
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	21 Dec 2020 15:36:35
	(b) (4)	

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 15:36:35

US3512199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:49:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 15:36:35

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:49:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:17
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:06:20

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Sep 2020 21:10:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:10:59
Data point term sent to Coder	System	02 Sep 2020 21:08:12
User entered 'levothyroxine'	Taylor Johnson (b) (4) (b) (4)	02 Sep 2020 21:07:29

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'hypothyroidism'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '175'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'ug (ug)'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'un UNK 2010'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Taylor Johnson (b) (4)	02 Sep 2020 21:07:29
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:07:29

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:07:29

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:07:29

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
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: NICARDIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 06:38:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:38:39
Data point term sent to Coder	System	02 Sep 2020 21:51:22
User entered 'NICARDIPINE'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:50:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'HYPERTENSION'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:50:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '60'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'twice daily (BID)'	Allison Crain (b) (4)	02 Sep 2020 21:50:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	02 Sep 2020 21:50:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 21:50:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:50:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:50:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:50:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 06:03:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:03:35
Data point term sent to Coder	System	02 Sep 2020 21:51:23
User entered 'FENOFIBRIC ACID'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'HIGH TRIGLYCERIDES'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '135'	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (ORAL)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:51:15
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:51:15

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PITAVASTATIN CALCIUM, PRODUCTSYNONYM: LIVALO - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Sep 2020 21:53:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:53:18
Data point term sent to Coder	System	02 Sep 2020 21:52:24
User entered 'LIVALO'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:52:01
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'HIGH CHOLESTEROL'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:52:01
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '2'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	02 Sep 2020 21:52:01
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	02 Sep 2020 21:52:01
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 21:52:01
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:52:01
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:52:01

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
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)	02 Sep 2020 21:53:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:53:49
Data point term sent to Coder	System	02 Sep 2020 21:53:25
User entered 'METOPROLOL'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:52:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'HYPERTENSION'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:52:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 05:05:58
Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:44:09
User entered '50' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:43:59
User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of tablet as there are various dosages available for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:01:23
User entered '3'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)' reason for change: New Information	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:43:59
User entered 'tablet (TABLET)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4) Brenda Anderson (b) (4)	04 Nov 2020 14:43:59
User entered 'once daily (QD)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'takes 2 tabs in the morning and 1 tab in the evening.' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	04 Nov 2020 14:43:59
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	02 Sep 2020 21:52:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 21:52:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:52:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:52:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 14:43:59
User entered '1'	System	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 14:43:59
User entered '1'	System	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 14:43:59
User entered '804 (804)'	System	02 Sep 2020 21:52:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Sep 2020 21:53:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Sep 2020 21:53:50
Data point term sent to Coder	System	02 Sep 2020 21:53:27
User entered 'METFORMIN'	Allison Crain (b) (4)	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'TYPE 2 DIABETES'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '1000'	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'twice daily (BID)'	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2010'	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:53:27
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:53:27

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
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.	(b) (4) Coder Import (b) (4)	02 Sep 2020 21:55:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:55:53
Data point term sent to Coder	System	02 Sep 2020 21:54:30
User entered 'ZOLPIDEM'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:58

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'INSOMNIA'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '10'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:58

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:58

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:53:58

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2016'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:53:58
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:53:58

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:53:58

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:53:58

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:56:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:56:58
Data point term sent to Coder User entered 'TRULICITY'	System Allison Crain (b) (4)	02 Sep 2020 21:55:34 02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'TYPE 2 DIABETES'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection as the dose per injection may vary. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 07:28:11
Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection as the dose per injection may vary. Please update as appropriate or provide clarification. ' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 12:44:49
User entered '1.5' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	12 Nov 2020 12:44:41
User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection as the dose per injection may vary. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:02:50
User entered '1'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Brenda Anderson (b) (4)	12 Nov 2020 12:44:41
User entered 'Other (OTHER)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	12 Nov 2020 12:44:41
	(b) (4)	
User entered 'INJECTION'	Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'every week (QS)'	Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '01 May 2020'	Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:55:26
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	02 Sep 2020 21:55:26

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Sep 2020 21:57:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:57:48
Data point term sent to Coder	System	02 Sep 2020 21:56:35
User entered 'GLIMEPIRIDE'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:56:06

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'TYPE 2 DIABETES'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '1'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'mg (mg)'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:56:06

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'twice daily (BID)'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (ORAL)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:56:06

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '01 Sep 2020'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:56:06
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 21:56:06

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:56:06

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:56:06

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Sep 2020 21:58:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Sep 2020 21:58:47
Data point term sent to Coder User entered 'ASPIRIN'	System Allison Crain (b) (4)	02 Sep 2020 21:57:36 02 Sep 2020 21:56:38

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'PROPHYLAXIS FOR CORONARY ARTERY DISEASE'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:56:38

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '81'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'mg (mg)'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:56:38

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (ORAL)'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:56:38

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2015'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:56:38
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:56:38

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:56:38

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:56:38

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
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.	Coder Import (b) (4)	02 Sep 2020 21:59:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:59:51
Data point term sent to Coder User entered 'AMLODIPINE'	System Allison Crain (b) (4)	02 Sep 2020 21:58:39 02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'HYPERTENSION'	(b) (4) Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '10'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)'	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'once daily (QD)'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'UN UNK 2019'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered '0'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	02 Sep 2020 21:57:47
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 21:57:47

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 17:18:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 17:18:41
Data point term sent to Coder Coding entries removed.	System Brenda Anderson (b) (4)	08 Jan 2021 17:10:54 08 Jan 2021 17:10:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Nov 2020 19:51:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Nov 2020 19:51:34
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	12 Nov 2020 14:29:47 12 Nov 2020 14:29:46

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 01:07:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 01:07:49
Data point term sent to Coder	System	10 Sep 2020 22:11:21
User entered 'Aleve'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'WORSENING RIGHT SHOULDER SORENESS SECONDARY TO YARD WORK' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	08 Jan 2021 17:10:05
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match the condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:22:25
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match the condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify. ' answered with 'Added as an AE' (Site from DM).	Allison Crain (b) (4) (b) (4)	12 Nov 2020 14:29:57
User entered 'RIGHT SHOULDER SORENESS SECONDARY TO YARD WORK' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	12 Nov 2020 14:29:46
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match the condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:00:56
User entered 'Shoulder soreness'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '220'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'mg (mg)'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'once (ONCE)'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered empty.	(b) (4) Sheldon Warren (b) (4)	10 Sep 2020 22:10:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '8 Sep 2020'	(b) (4) Sheldon Warren (b) (4)	10 Sep 2020 22:10:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	10 Sep 2020 22:10:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '8 Sep 2020'	(b) (4) Sheldon Warren (b) (4)	10 Sep 2020 22:10:48
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User entered empty.	System	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User entered empty.	System	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:38:55
User entered empty.	System	10 Sep 2020 22:10:48

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
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)	07 Oct 2020 16:16:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:16:15
Data point term sent to Coder	System	07 Oct 2020 16:15:42
User entered 'INFLuenza vaccine'	Sheldon Warren (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'seasonal influenza'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '1'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Other (OTHER)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'injection'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 16:15:14
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'once (ONCE)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'Intramuscular (INTRAMUSCULAR)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '16 Sep 2020'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 16:15:14
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered '0'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '16 Sep 2020'	(b) (4) Sheldon Warren (b) (4)	07 Oct 2020 16:15:14
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	Sheldon Warren (b) (4) (b) (4)	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User entered empty.	System	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User entered empty.	System	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:39:01
User entered empty.	System	07 Oct 2020 16:15:14

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Nov 2020 16:40:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:40:45
Data point term sent to Coder User entered 'ALEVE'	System Allison Crain (b) (4) (b) (4)	18 Nov 2020 16:39:22 18 Nov 2020 16:39:19

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'RIGHT SHOULDER PAIN'	(b) (4) Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '220'	(b) (4) Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'mg (mg)'	Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	18 Nov 2020 16:39:19

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'as needed (PRN)'	(b) (4) Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'Oral (ORAL)'	(b) (4) Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered empty.	Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered 'UN UNK 2018'	(b) (4) Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User entered '0'	(b) (4) Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 21:38:15
User entered empty.	Allison Crain (b) (4) (b) (4)	18 Nov 2020 16:39:19

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	18 Nov 2020 16:39:19
	(b) (4)	

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:39:19

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:39:19

US3512199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:39:19

US3512199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:49:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:43:03
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	01 Mar 2021 16:05:28
	(b) (4)	

US3512199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:49

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:07:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Per CDM: Date of discontinuation does not match with the date of dose discontinued 30 SEP 2020 (Visit 2 day 29 (1)). Please review and update the date accordingly.' (Site from DM).	(b) (4)	
Query 'Per CDM: Date of discontinuation does not match with the date of dose discontinued 30 SEP 2020 (Visit 2 day 29 (1)). Please review and update the date accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 11:54:27
Query 'Per CDM: Date of discontinuation does not match with the date of dose discontinued 30 SEP 2020 (Visit 2 day 29 (1)). Please review and update the date accordingly.' answered with 'site used the 02 sep 2020 date because that was the day the swab was completed and confirmed positive. Site changed data per query guidance.' (Site from DM).	Brenda Anderson (b) (4)	16 Dec 2020 17:46:08
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 17:45:42
User opened query 'Per CDM: Date of discontinuation does not match with the date of dose discontinued 30 SEP 2020 (Visit 2 day 29 (1)). Please review and update the date accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:16:34
User entered '2 Sep 2020'	Brenda Anderson (b) (4)	10 Dec 2020 13:21:35
	(b) (4)	

US3512199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:07:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
User closed query 'Per CDM: Primary reason for Dosing Discontinuation is SARS-COV-2. Please review and update AE form accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:58:18
Query 'Per CDM: Primary reason for Dosing Discontinuation is SARS-COV-2. Please review and update AE form accordingly.' answered with 'added AE' (Site from DM).	Brenda Anderson (b) (4)	21 Dec 2020 15:43:30
User opened query 'Per CDM: Primary reason for Dosing Discontinuation is SARS-COV-2. Please review and update AE form accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 11:55:25
Query ' Per CDM: Please update the AE form and consider to update this field to AE (specify) or SAE (specify) accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:38:10
User opened query ' Per CDM: Please update the AE form and consider to update this field to AE (specify) or SAE (specify) accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:20:00
User entered 'Due to SARS-COV-2 (COVID)'	Brenda Anderson (b) (4)	10 Dec 2020 13:21:35

US3512199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:49

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:07:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 21:38:15
Query 'Per CDM: If the primary reason for dosing discontinuation is AE or SAE , please provide AE or SAE log line number (i.e. AE#1 or SAE#1, etc.)' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 12:38:13
User opened query 'Per CDM: If the primary reason for dosing discontinuation is AE or SAE , please provide AE or SAE log line number (i.e. AE#1 or SAE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:22:51
User entered empty.	Brenda Anderson (b) (4) (b) (4)	10 Dec 2020 13:21:35