

US3902030 (Prod: Synexus - Optimal Research - Melbourne)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:44:45

All time stamps listed in this document are displayed in GMT

US3902030

Form: Participant Creation

Data signed: (b) (4) 30 Mar 2021 18:11:37

Generated On: 12 Aug 2021 13:44:45

[Participant ID](#)

US3902030

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

US3902030

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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) 30 Mar 2021 18:11:39

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Date of Informed Consent (*dd MMM yyyy*) 03 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 30 Mar 2021 18:11:39

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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) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Condition	GASTROESOPHOGEAL REFLUX DISEASE
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 (4)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Condition	RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	16 JAN 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)	16 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	16 JAN 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)	16 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Condition	INGUINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:00 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 16:00
Height (<i>xxx.x</i>)	66.0 in
Weight (<i>xxx.x</i>)	228.0 lb
BMI (<i>xxx.x</i>)	36.87711 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:39

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Mar 2021 18:11:39

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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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Mar 2021 18:11:39

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189616

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) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 16:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	18:10 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 18:10
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 17:29 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 17:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 SEP 2020
Collection time (00:00-23:59)	16:43 (24 HR)
Collection date and time (derived)	03 SEP 2020 16:43

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:44	03 SEP 2020 16:44
Nasopharyngeal Swab 2	Yes	16:44	03 SEP 2020 16:44

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 18:10

PC Open Date & Time

03 SEP 2020 17:49

PC Close Date & Time

03 SEP 2020 20:19

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.4 °F

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

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

PC Time Stamp	04 SEP 2020 08:52
PC Open Date & Time	03 SEP 2020 21:14
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 10:44

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

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	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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	06 SEP 2020 08:51
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

08 SEP 2020 12:45

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 08:48

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 18:12

PC Open Date & Time

03 SEP 2020 17:49

PC Close Date & Time

03 SEP 2020 20:19

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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

04 SEP 2020 08:52

PC Open Date & Time

03 SEP 2020 21:14

PC Close Date & Time

04 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 10:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 08:52

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

12

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:46

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 08:51

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 18:13
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PC Open Date & Time	03 SEP 2020 17:49
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PC Close Date & Time	03 SEP 2020 20:19
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US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 08:56
PC Open Date & Time	03 SEP 2020 21:14
PC Close Date & Time	04 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

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 ☒

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 10:47
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 09:39
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

		Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 16:22	
PC Open Date & Time	08 SEP 2020 12:00	
PC Close Date & Time	09 SEP 2020 11:59	

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

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 ☒

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 08:52
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 8

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 11 SEP 2020 09:26

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

2

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

PC Time Stamp

11 SEP 2020 09:27

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

2

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

PC Time Stamp

12 SEP 2020 09:02

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 10

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

2

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

PC Time Stamp

13 SEP 2020 09:37

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 11

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

2

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

PC Time Stamp

14 SEP 2020 00:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 12

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

15 SEP 2020 09:50

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

11 SEP 2020 09:27

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

12 SEP 2020 09:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

13 SEP 2020 09:37

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

14 SEP 2020 00:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

15 SEP 2020 09:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 SEP 2020 09:28

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 SEP 2020 09:03

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 10

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

13 SEP 2020 09:37

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 11

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

14 SEP 2020 00:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 12

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

15 SEP 2020 09:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 11 SEP 2020 09:28

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 12 SEP 2020 09:03

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

13 SEP 2020 09:38

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 14 SEP 2020 00:01

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 SEP 2020 09:51

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:44:45

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	11 SEP 2020 09:29
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 09:04
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 10
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	13 SEP 2020 09:38
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 SEP 2020 00:01
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 12

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

No ☒

Yes ☐

PC Time stamp

15 SEP 2020 09:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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 HIVES ARE GOING AWAY, NO
OTHER CHANGES

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

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)	1 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:10
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3902030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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.

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

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

PHYSICIAN DECIDED BASED ON ADVERSE REACTION TO FIRST VACCINATION

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? _____

US3902030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	1 OCT 2020
-------------------------------	------------

Collection time (00:00-23:59)	11:52 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	1 OCT 2020 11:52
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US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:53	1 OCT 2020 11:53
Nasopharyngeal Swab 2	No		

US3902030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

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) _____

US3902030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

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.

US3902030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

10:50 (24 HR)

Collection date and time (derived)

26 OCT 2020 10:50

US3902030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

04 NOV 2020 08:36:54

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

10 NOV 2020 08:24:35

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

Date and time of submission

21 NOV 2020 08:06:37

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 DEC 2020 12:00:34
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 08:20:06
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

16 DEC 2020 12:09:45

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 07:26:39
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 12:01:18

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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	02 JAN 2021 10:30:48
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 19:59:14
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 10:32:52

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 145

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐ Yes ☐

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 180

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 187

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 208

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 215

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 229

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

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

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

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

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

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

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 236

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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09 MAR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

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30 MAR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

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02 APR 2022 00:01

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06 APR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

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13 APR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

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27 APR 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

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04 MAY 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

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01 JUN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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 ☐

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3902030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3902030

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:39

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

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

Visit date (dd MMM yyyy)	19 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:41:57

Generated On: 12 Aug 2021 13:44:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 10:04
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

10:31 (24 HR)

Collection date and time (derived)

19 MAR 2021 10:31

US3902030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:11:40

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

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

US3902030

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3902030

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:44:45

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:44:45

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

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

Visit date (dd MMM yyyy)	1 FEB 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
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US3902030

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

Form: Unblinding

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Date of updated informed consent (dd MMM yyyy) 1 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒
No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐
Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 1 FEB 2021

Participant randomization assignment mRNA-1273 ☒
Placebo ☐

Actual Dose 1 mRNA-1273 ☒
Placebo ☐
Not Administered ☐

Actual Dose 2 mRNA-1273 ☐
Placebo ☐
Not Administered ☒

Will participant receive mRNA-1273? Yes ☐
No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3902030

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	1 FEB 2021
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Collection time (00:00-23:59)	14:58 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	1 FEB 2021 14:58
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US3902030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 1 FEB 2021

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

Collection Date and Time (derived) 1 FEB 2021 14:59

US3902030

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 30 Mar 2021 18:11:37

Generated On: 12 Aug 2021 13:44:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3902030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	HIVES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3902030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	SORE HANDS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	SWOLLEN LIPS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	8 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 18:13:07

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	UPPER RESPIRATORY INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 18:13:07

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	ARTHRALGIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	MYALGIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 18:13:07

Generated On: 12 Aug 2021 13:44:45

AEID	
Adverse event	INJECTION SITE REDNESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 18:11:38

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Name of Medication NOVOLIN 70/30

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 25

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication METFORMIN HCL

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

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 (2)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 18:11:38

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Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Mar 2021 18:11:38

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Name of Medication LYRICA

Prophylaxis Yes ☐
No ☒

Indication PERIPHERAL NEUROPATHY

Dose per administration 300

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication LOVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTROLEMIA

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	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	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication HIVES

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 18 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication NOVOLIN 70/30

Prophylaxis Yes ☐
No ☒

Indication DIABETES II

Dose per administration 25

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication NOVOLIN 70/30

Prophylaxis Yes ☐
No ☒

Indication DIABETES II

Dose per administration 20

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

NIGHTLY

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 08 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication AE #4: UPPER RESPIRATORY INFECTION

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3902030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 20:42:44

Generated On: 12 Aug 2021 13:44:45

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 NOV 2020	HIATAL HERNIA REPAIR	Medical History	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 30 Mar 2021 18:11:38

Generated On: 12 Aug 2021 13:44:45

Date of dosing discontinuation (dd MMM yyyy) 1 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #1

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:44:45

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

US3902030 (Prod: Synexus - Optimal Research - Melbourne)

US3902030

Form: Participant Creation

Generated On: 12 Aug 2021 13:44:45

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:39:55
User entered 'US3902030'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:54:35

US3902030

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:11:41
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:13

US3902030

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:11:41
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:54:36

US3902030

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:11:41
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:13

US3902030

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'SCRN'	System	03 Sep 2020 21:36:13

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:54:37

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '66'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'YEARS'	System	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '66'	System	03 Sep 2020 21:37:01

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered 'Male (M)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered 'l'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '0'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '0'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '0'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '0'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '0'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered empty.	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '0'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:44:45

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:06
User entered '0'	Taylor Atkinson (b) (4)	03 Sep 2020 21:36:47

US3902030

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:56:31
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 03-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:22:32
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 03-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	07 Nov 2020 16:14:49
DataPoint Un-verified.	(b) (4)	
User entered '03 Sep 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	07 Nov 2020 16:14:44
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 03-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 10:45:02
User entered '3 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:21:25
	Taylor Atkinson (b) (4)	03 Sep 2020 21:37:01
	(b) (4)	

US3902030

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Sep 2020'	System	03 Sep 2020 21:37:01

US3902030

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2020'	System	03 Sep 2020 21:37:01

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:25
User entered 'Amendment 3 (3)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:37:01

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:25
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:37:01

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:25
User entered empty.	Taylor Atkinson (b) (4)	03 Sep 2020 21:37:01

US3902030

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:25
User entered empty.	Taylor Atkinson (b) (4)	03 Sep 2020 21:37:01

US3902030

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:25
User entered 'No (N)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:37:01

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:54:36

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:44:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'I'	System	03 Sep 2020 21:37:10

US3902030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:34
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:37:10

US3902030

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:44:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:21:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:14:26

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Metabolism and nutrition disorders, HLG: 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)	08 Sep 2020 14:15:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:15:42
Data point term sent to Coder	System	08 Sep 2020 14:14:58
User entered 'Diabetes Type 2'	(b) (4), (b) (6)	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2014'	(b) (4), (b) (6)	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2014'	System	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2014'	System	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:14:51

US3902030

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:16:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:16:46
Data point term sent to Coder	System	08 Sep 2020 14:16:01
User entered 'Hypertension'	(b) (4), (b) (6)	08 Sep 2020 14:15:08

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Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2014'	(b) (4), (b) (6)	08 Sep 2020 14:15:08

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Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:15:08

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Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:15:08

US3902030

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:15:08

US3902030

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:15:08

US3902030

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2014'	System	08 Sep 2020 14:15:08

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Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2014'	System	08 Sep 2020 14:15:08

US3902030

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:15:08

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Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:15:08

US3902030

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:16:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:16:47
Data point term sent to Coder	System	08 Sep 2020 14:16:01
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	08 Sep 2020 14:15:34

US3902030

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2018'	(b) (4), (b) (6)	08 Sep 2020 14:15:34

US3902030

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:15:34

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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:15:34

US3902030

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:15:34

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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:15:34

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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2018'	System	08 Sep 2020 14:15:34

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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2018'	System	08 Sep 2020 14:15:34

US3902030

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:15:34

US3902030

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:15:34

US3902030

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
Query 'Per DM CLR: Please verify the type of the PERIPHERAL NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:55:26
User opened query 'Per DM CLR: Please verify the type of the PERIPHERAL NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:12:38
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:17:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:17:27
Data point term sent to Coder	System	08 Sep 2020 14:15:59
User entered 'Peripheral Neuropathy'	(b) (4), (b) (6)	08 Sep 2020 14:15:54

US3902030

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN Mar 2020'	(b) (4), (b) (6)	08 Sep 2020 14:15:54

US3902030

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:15:54

US3902030

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:15:54

US3902030

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:15:54

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Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:15:54

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Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Mar 2020'	System	08 Sep 2020 14:15:54

US3902030

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2020'	System	08 Sep 2020 14:15:54

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Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:15:54

US3902030

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:15:54

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:17:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:17:44
Data point term sent to Coder	System	08 Sep 2020 14:17:02
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2018'	(b) (4), (b) (6)	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2018'	System	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2018'	System	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	08 Sep 2020 14:16:33

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:41:25
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:30
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:17:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 14:18:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 14:18:44
Data point term sent to Coder	System	08 Sep 2020 14:18:03
User entered 'Right Knee Replacement'	(b) (4), (b) (6)	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '16 Jan 2020'	(b) (4), (b) (6)	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '16 Jan 2020'	(b) (4), (b) (6)	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2020'	System	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2020'	System	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2020'	System	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2020'	System	08 Sep 2020 14:17:09

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:41:30
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:37
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:17:54
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 14:18:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 14:18:43
Data point term sent to Coder	System	08 Sep 2020 14:18:04
User entered 'Left Knee Replacement'	(b) (4), (b) (6)	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '16 Jan 2020'	(b) (4), (b) (6)	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '16 Jan 2020'	(b) (4), (b) (6)	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2020'	System	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2020'	System	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2020'	System	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2020'	System	08 Sep 2020 14:17:26

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:19:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:19:44
Data point term sent to Coder	System	08 Sep 2020 14:19:05
User entered 'Hiatal hernia'	(b) (4), (b) (6)	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2016'	(b) (4), (b) (6)	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2019'	(b) (4), (b) (6)	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2016'	System	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2016'	System	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2019'	System	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2019'	System	08 Sep 2020 14:18:23

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:19:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:19:45
Data point term sent to Coder	System	08 Sep 2020 14:19:05
User entered 'Cholecystitis'	(b) (4), (b) (6)	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'Un UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:18:39

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Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2017'	System	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2017'	System	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2017'	System	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2017'	System	08 Sep 2020 14:18:39

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Surgical and medical procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:19:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:19:44
Data point term sent to Coder	System	08 Sep 2020 14:19:06
User entered 'Cholecystectomy'	(b) (4), (b) (6)	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'Un UNK 2017'	(b) (4), (b) (6)	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2017'	System	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2017'	System	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2017'	System	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2017'	System	08 Sep 2020 14:19:01

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:22:43
Data point term sent to Coder	System	08 Sep 2020 14:22:11
User entered 'Inguinal Hernia'	(b) (4), (b) (6)	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 1972'	(b) (4), (b) (6)	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered 'UN UNK 1972'	(b) (4), (b) (6)	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:24:40
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 1972'	System	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '1972'	System	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 1972'	System	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '1972'	System	08 Sep 2020 14:21:31

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 03:26:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 03:26:49
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:27
Data point term sent to Coder	System	29 Oct 2020 11:55:27
User entered 'Osteoarthritis of Knees'	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:27
User entered 'un UNK 2015'	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:27
User entered '0'	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:27
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:27
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:27
User entered '0'	Taylor Atkinson (b) (4)	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'Jan 2015'	System	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '2015'	System	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered empty.	System	29 Oct 2020 11:55:06

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered '16:00'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '03 Sep 2020 16:00'	System	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered '66.0' in	(b) (4), (b) (6)	08 Sep 2020 14:20:07
DataPoint set to visible.	System	03 Sep 2020 21:37:10

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered '228.0' lb	(b) (4), (b) (6)	08 Sep 2020 14:20:07
DataPoint set to visible.	System	03 Sep 2020 21:37:10

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '36.87711'	System	08 Sep 2020 14:20:07
DataPoint set to visible.	System	03 Sep 2020 21:37:10

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'kg/m2'	System	08 Sep 2020 14:20:07
DataPoint set to visible.	System	03 Sep 2020 21:37:10

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 08:15:34
	(b) (4), (b) (6)	16 Sep 2020 17:25:49
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' answered with 'Updated and corrected. Thank you!' (Site from DM).	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Sep 2020 15:31:26
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:15:16
User entered '97.8' F	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered empty; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:26
User entered '91'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'bpm'	System	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:26
User entered '18'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'breaths/min'	System	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:26
User entered '118'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'mmHg'	System	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:26
User entered '75'	(b) (4), (b) (6)	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'mmHg'	System	08 Sep 2020 14:20:07

US3902030

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44

US3902030

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:20:55

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Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:25:59
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:20:55

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:44:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:29
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:22:14

US3902030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:22:28

US3902030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:56
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:22:28

US3902030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:26:56
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 14:22:28

US3902030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'VISIT1'	System	08 Sep 2020 14:22:28

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 20:59:25

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered '189616'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 20:59:25

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 20:59:25

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

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)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:23:34

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

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)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:23:34

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:23:34

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:23:34

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:31
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 14:23:34

US3902030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:44:45

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:58:17
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'please provide data' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 14:35:44
Query 'please provide data' answered with 'updated' (Site from CRA).	Taylor Atkinson (b) (4)	29 Oct 2020 11:33:35
User entered 'No (N)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:33:29
User opened query 'please provide data' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:47:25
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:17:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:17:53

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:44:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:49
User entered '66.0' in	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:44:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:49
User entered '228.0' lb	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:44:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:49
User entered '66.0' in	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:44:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:49
User entered '228.0' lb	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '16:00'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '03 Sep 2020 16:00'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '97.8' F	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '91'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'bpm'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '18'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'breaths/min'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '118'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'mmHg'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '75'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'mmHg'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:44:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:49
User entered '66.0' in	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:44:45

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:27:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:31:49
User entered '228.0' lb	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '18:10'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '03 Sep 2020 18:10'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '97.5' F	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '92'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'bpm'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '14'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'breaths/min'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '121'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'mmHg'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 18:02:19
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'As per PI, NCS' (Site from DM).	Taylor Atkinson (b) (4)	13 Nov 2020 23:37:49
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:21:12
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:07
User entered '91'	(b) (4), (b) (6)	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'mmHg'	System	08 Sep 2020 14:25:20

US3902030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:18
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:32:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:25:29

US3902030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:18
User entered empty; reason for change Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:32:03
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:25:29

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:27
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 21:38:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 21:38:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Sep 2020 21:38:33
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 21:38:23
User entered empty.	Taylor Atkinson (b) (4)	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:27
User entered empty.	Taylor Atkinson (b) (4)	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

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)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:27
User entered empty.	Taylor Atkinson (b) (4)	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 21:38:33
User entered empty.	System	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:59:00
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format. Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:20:57
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format. Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you.' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	03 Nov 2020 18:41:15
DataPoint Un-verified.	Taylor Atkinson (b) (4)	03 Nov 2020 18:41:08
User entered '03 Sep 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 18:41:08
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format. Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:27:28
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:27
User entered '3 Sep 2020'	Taylor Atkinson (b) (4)	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:27
User entered '17:29'	Taylor Atkinson (b) (4)	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '03 Sep 2020 17:29'	System	03 Nov 2020 18:41:08
User entered '3 Sep 2020 17:29'	System	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:27
User entered 'Left Arm (LEFT ARM)'	Taylor Atkinson (b) (4)	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:29:27
User entered 'ONCE'	System	03 Sep 2020 21:38:33
User entered empty.	System	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 21:38:33
User entered empty.	System	03 Sep 2020 21:38:23

US3902030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:30:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:25:55

US3902030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:30:29
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:25:55

US3902030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:30:29
User entered '16:43'	(b) (4), (b) (6)	08 Sep 2020 14:25:55

US3902030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '03 Sep 2020 16:43'	System	08 Sep 2020 14:25:55

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:31:22
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:31:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:31:22
User entered '16:44'	(b) (4), (b) (6)	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '03 Sep 2020 16:44'	System	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:31:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:31:22
User entered '16:44'	(b) (4), (b) (6)	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '03 Sep 2020 16:44'	System	08 Sep 2020 14:26:26

US3902030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:32:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 14:26:31

US3902030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '1'	System	08 Sep 2020 14:26:31

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:09:07', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '2d4377ca-23bd-4fb6-931a-8e30940bf05b' User entered 'Yes (Y)'	System	03 Sep 2020 22:10:33
	System	03 Sep 2020 22:10:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:08:11', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '2d4377ca-23bd-4fb6-931a-8e30940bf05b' User entered '97.5'	System	03 Sep 2020 22:10:33
	System	03 Sep 2020 22:10:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:10:17', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '2d4377ca-23bd-4fb6-931a-8e30940bf05b' User entered 'No (N)'	System	03 Sep 2020 22:10:33
	System	03 Sep 2020 22:10:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:10:30', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '2d4377ca-23bd-4fb6-931a-8e30940bf05b' User entered '03 Sep 2020 18:10'	System	03 Sep 2020 22:10:33
	System	03 Sep 2020 22:10:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 17:49'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 20:19'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:52:42', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'dbb56800-4cb4-440c-aa2b-f50695d06012' User entered 'Yes (Y)'	System	04 Sep 2020 12:53:02
	System	04 Sep 2020 12:53:02

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:52:50', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'dbb56800-4cb4-440c-aa2b-f50695d06012' User entered '96.4'	System	04 Sep 2020 12:53:02
	System	04 Sep 2020 12:53:02

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:52:55', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'dbb56800-4cb4-440c-aa2b-f50695d06012'	System	04 Sep 2020 12:53:02
User entered 'No (N)'	System	04 Sep 2020 12:53:02

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:52:59', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'dbb56800-4cb4-440c-aa2b-f50695d06012' User entered '04 Sep 2020 08:52'	System	04 Sep 2020 12:53:02
	System	04 Sep 2020 12:53:02

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 21:14'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 2'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:35:49', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5ede7933-a4e2-44b8-86ad-5ad1b82a97a0' User entered 'Yes (Y)'	System	05 Sep 2020 14:44:33
	System	05 Sep 2020 14:44:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:44:21', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5ede7933-a4e2-44b8-86ad-5ad1b82a97a0' User entered '96.1'	System	05 Sep 2020 14:44:33
	System	05 Sep 2020 14:44:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:44:27', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5ede7933-a4e2-44b8-86ad-5ad1b82a97a0'	System	05 Sep 2020 14:44:33
User entered 'No (N)'	System	05 Sep 2020 14:44:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:44:32', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5ede7933-a4e2-44b8-86ad-5ad1b82a97a0' User entered '05 Sep 2020 10:44'	System	05 Sep 2020 14:44:33
	System	05 Sep 2020 14:44:33

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 3'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:50:47', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '21e9face-7de5-4e37-ad67-1f62961558cf' User entered 'Yes (Y)'	System	06 Sep 2020 12:51:20
	System	06 Sep 2020 12:51:20

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:50:57', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '21e9face-7de5-4e37-ad67-1f62961558cf' User entered '98.4'	System	06 Sep 2020 12:51:20
	System	06 Sep 2020 12:51:20

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:50:24', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '21e9face-7de5-4e37-ad67-1f62961558cf' User entered 'Yes (Y)'	System	06 Sep 2020 12:51:20
	System	06 Sep 2020 12:51:20

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
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 'Updated' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 12:40:50
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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:50:35', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '21e9face-7de5-4e37-ad67-1f62961558cf' User entered '1'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:46
	System	06 Sep 2020 12:51:20
	System	06 Sep 2020 12:51:20
	System	06 Sep 2020 12:51:20

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:50:35', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '21e9face-7de5-4e37-ad67-1f62961558cf' User entered '0'	System	06 Sep 2020 12:51:20
	System	06 Sep 2020 12:51:20

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:51:15', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '21e9face-7de5-4e37-ad67-1f62961558cf' User entered '06 Sep 2020 08:51'	System	06 Sep 2020 12:51:20
	System	06 Sep 2020 12:51:20

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 4'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 5'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 6'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:44:57', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f92d3d39-458f-4f8b-a7c0-66deec2754d1' User entered 'Yes (Y)'	System	08 Sep 2020 16:45:46
	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:45:12', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f92d3d39-458f-4f8b-a7c0-66deec2754d1' User entered '97.4'	System	08 Sep 2020 16:45:46
	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:45:18', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f92d3d39-458f-4f8b-a7c0-66deec2754d1'	System	08 Sep 2020 16:45:46
User entered 'Yes (Y)'	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
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 'Confirmed. Con meds are being updated' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 05:07:55
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).	Taylor Atkinson (b) (4)	16 Sep 2020 15:34:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:45:30', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f92d3d39-458f-4f8b-a7c0-66deec2754d1'	System	08 Sep 2020 16:45:46
User entered '1'	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:45:30', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f92d3d39-458f-4f8b-a7c0-66deec2754d1' User entered '0'	System	08 Sep 2020 16:45:46
	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:45:42', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f92d3d39-458f-4f8b-a7c0-66deec2754d1' User entered '08 Sep 2020 12:45'	System	08 Sep 2020 16:45:46
	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 7'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:47:52', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1b5afab-85b3-42e6-a65b-70948fc7314d' User entered 'Yes (Y)'	System	10 Sep 2020 12:48:06
	System	10 Sep 2020 12:48:06

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:47:57', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1b5afab-85b3-42e6-a65b-70948fc7314d' User entered '98.5'	System	10 Sep 2020 12:48:06
	System	10 Sep 2020 12:48:06

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:48:00', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1b5afab-85b3-42e6-a65b-70948fc7314d' User entered 'No (N)'	System	10 Sep 2020 12:48:06
	System	10 Sep 2020 12:48:06

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:48:05', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1b5afab-85b3-42e6-a65b-70948fc7314d' User entered '10 Sep 2020 08:48'	System	10 Sep 2020 12:48:06
	System	10 Sep 2020 12:48:06

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:11:19', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '866a9aad-f1ea-40a3-ab78-90f2a3e9b950'	System	03 Sep 2020 22:12:18
User entered 'None (1)'	System	03 Sep 2020 22:12:18

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:11:25', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '866a9aad-f1ea-40a3-ab78-90f2a3e9b950'	System	03 Sep 2020 22:12:18
User entered 'No (N)'	System	03 Sep 2020 22:12:18

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:11:30', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '866a9aad-f1ea-40a3-ab78-90f2a3e9b950'	System	03 Sep 2020 22:12:18
User entered 'No (N)'	System	03 Sep 2020 22:12:18

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:11:59', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '866a9aad-f1ea-40a3-ab78-90f2a3e9b950'	System	03 Sep 2020 22:12:18
User entered 'None (1)'	System	03 Sep 2020 22:12:18

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:12:15', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '866a9aad-f1ea-40a3-ab78-90f2a3e9b950'	System	03 Sep 2020 22:12:18
User entered '03 Sep 2020 18:12'	System	03 Sep 2020 22:12:18

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 17:49'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 20:19'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:50:47', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd33e7a84-0e3c-49fb-8d64-5e177c236703'	System	04 Sep 2020 12:52:31
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 12:52:31

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:51:34', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd33e7a84-0e3c-49fb-8d64-5e177c236703' User entered 'No (N)'	System	04 Sep 2020 12:52:31
	System	04 Sep 2020 12:52:31

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:51:47', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd33e7a84-0e3c-49fb-8d64-5e177c236703' User entered 'No (N)'	System	04 Sep 2020 12:52:31
	System	04 Sep 2020 12:52:31

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:52:13', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd33e7a84-0e3c-49fb-8d64-5e177c236703'	System	04 Sep 2020 12:52:31
User entered 'None (1)'	System	04 Sep 2020 12:52:31

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:52:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd33e7a84-0e3c-49fb-8d64-5e177c236703'	System	04 Sep 2020 12:52:31
User entered '04 Sep 2020 08:52'	System	04 Sep 2020 12:52:31

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 21:14'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 2'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:45:20', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a06d0823-6656-4c87-93ab-3c2269f1d37b'	System	05 Sep 2020 14:46:10
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 14:46:10

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:45:45', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a06d0823-6656-4c87-93ab-3c2269f1d37b'	System	05 Sep 2020 14:46:10
User entered 'No (N)'	System	05 Sep 2020 14:46:10

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:45:52', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a06d0823-6656-4c87-93ab-3c2269f1d37b'	System	05 Sep 2020 14:46:10
User entered 'No (N)'	System	05 Sep 2020 14:46:10

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:46:01', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a06d0823-6656-4c87-93ab-3c2269f1d37b'	System	05 Sep 2020 14:46:10
User entered 'None (1)'	System	05 Sep 2020 14:46:10

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:46:06', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a06d0823-6656-4c87-93ab-3c2269f1d37b'	System	05 Sep 2020 14:46:10
User entered '05 Sep 2020 10:46'	System	05 Sep 2020 14:46:10

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 3'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:51:55', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1e5af69-5c7c-4306-9053-3c1aeffe3238'	System	06 Sep 2020 12:52:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	06 Sep 2020 12:52:57

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:52:04', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1e5af69-5c7c-4306-9053-3c1aeffe3238'	System	06 Sep 2020 12:52:57
User entered 'No (N)'	System	06 Sep 2020 12:52:57

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:52:09', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1e5af69-5c7c-4306-9053-3c1aeffe3238'	System	06 Sep 2020 12:52:57
User entered 'No (N)'	System	06 Sep 2020 12:52:57

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:52:27', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1e5af69-5c7c-4306-9053-3c1aeffe3238'	System	06 Sep 2020 12:52:57
User entered 'None (1)'	System	06 Sep 2020 12:52:57

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T08:52:54', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b1e5af69-5c7c-4306-9053-3c1aeffe3238'	System	06 Sep 2020 12:52:57
User entered '06 Sep 2020 08:52'	System	06 Sep 2020 12:52:57

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 4'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 5'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 6'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:45:56', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '614def83-31c8-4c41-aa23-57c5f8ca8e1a' User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 16:46:52
	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:45:59', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '614def83-31c8-4c41-aa23-57c5f8ca8e1a' User entered 'Yes (Y)'	System	08 Sep 2020 16:46:52
	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:46:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '614def83-31c8-4c41-aa23-57c5f8ca8e1a' User entered '12'	System	08 Sep 2020 16:46:52
	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:46:34', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '614def83-31c8-4c41-aa23-57c5f8ca8e1a' User entered 'No (N)'	System	08 Sep 2020 16:46:52
	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:46:41', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '614def83-31c8-4c41-aa23-57c5f8ca8e1a'	System	08 Sep 2020 16:46:52
User entered 'None (1)'	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T12:46:50', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '614def83-31c8-4c41-aa23-57c5f8ca8e1a' User entered '08 Sep 2020 12:46'	System	08 Sep 2020 16:46:52
	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 7'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:49:08', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'cc957b4f-37d8-4aa0-a453-9fb2c9791015'	System	10 Sep 2020 12:51:04
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:49:14', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'cc957b4f-37d8-4aa0-a453-9fb2c9791015'	System	10 Sep 2020 12:51:04
User entered 'Yes (Y)'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:50:34', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'cc957b4f-37d8-4aa0-a453-9fb2c9791015' User entered '3'	System	10 Sep 2020 12:51:04
	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:50:43', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'cc957b4f-37d8-4aa0-a453-9fb2c9791015'	System	10 Sep 2020 12:51:04
User entered 'No (N)'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:50:52', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'cc957b4f-37d8-4aa0-a453-9fb2c9791015' User entered 'None (1)'	System	10 Sep 2020 12:51:04
	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:51:00', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'cc957b4f-37d8-4aa0-a453-9fb2c9791015'	System	10 Sep 2020 12:51:04
User entered '10 Sep 2020 08:51'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:12:59', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered 'None (0)'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:13:07', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered 'None (0)'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:13:12', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered 'None (0)'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:13:18', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered 'None (0)'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:13:22', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered 'None (0)'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:13:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered 'None (0)'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:13:39', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered 'No (N)'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-03T18:13:55', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '589f144f-0902-4be2-9ee2-40e0c887a2ee' User entered '03 Sep 2020 18:13'	System	03 Sep 2020 22:13:57
	System	03 Sep 2020 22:13:57

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 17:49'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 20:19'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:53:43', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60'	System	04 Sep 2020 12:56:56
User entered 'No interference with activity (1)'	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:54:13', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60'	System	04 Sep 2020 12:56:56
User entered 'None (0)'	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:54:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60'	System	04 Sep 2020 12:56:56
User entered 'No interference with activity (1)'	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:54:46', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60'	System	04 Sep 2020 12:56:56
User entered 'No interference with activity (1)'	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:54:55', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60' User entered 'None (0)'	System	04 Sep 2020 12:56:56
	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:55:30', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60'	System	04 Sep 2020 12:56:56
User entered 'No interference with activity (1)'	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:55:40', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60'	System	04 Sep 2020 12:56:56
User entered 'No (N)'	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-04T08:56:52', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'df8776c1-6578-4426-bd21-5c9e8f0b7f60'	System	04 Sep 2020 12:56:56
User entered '04 Sep 2020 08:56'	System	04 Sep 2020 12:56:56

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '03 Sep 2020 21:14'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 2'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:46:23', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03'	System	05 Sep 2020 14:47:28
User entered 'No interference with activity (1)'	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:46:36', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03'	System	05 Sep 2020 14:47:28
User entered 'Some interference with activity (2)'	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:46:48', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03'	System	05 Sep 2020 14:47:28
User entered 'No interference with activity (1)'	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:46:57', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03'	System	05 Sep 2020 14:47:28
User entered 'No interference with activity (1)'	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:47:02', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03' User entered 'None (0)'	System	05 Sep 2020 14:47:28
	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:47:11', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03'	System	05 Sep 2020 14:47:28
User entered 'No interference with activity (1)'	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:47:17', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03' User entered 'No (N)'	System	05 Sep 2020 14:47:28
	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-05T10:47:23', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f96512a-604f-4688-a47b-5bfbe9237e03'	System	05 Sep 2020 14:47:28
User entered '05 Sep 2020 10:47'	System	05 Sep 2020 14:47:28

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 3'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:38:21', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1'	System	06 Sep 2020 13:39:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:37:07', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1'	System	06 Sep 2020 13:39:42
User entered 'Some interference with activity (2)'	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:37:20', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1'	System	06 Sep 2020 13:39:42
User entered 'Some interference with activity (2)'	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:37:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1'	System	06 Sep 2020 13:39:42
User entered 'Some interference with activity (2)'	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:37:33', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1' User entered 'None (0)'	System	06 Sep 2020 13:39:42
	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:37:49', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1'	System	06 Sep 2020 13:39:42
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:38:01', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1' User entered 'No (N)'	System	06 Sep 2020 13:39:42
	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-06T09:39:41', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '89c958de-8fd1-4358-ac4a-75f31a7f02d1' User entered '06 Sep 2020 09:39'	System	06 Sep 2020 13:39:42
	System	06 Sep 2020 13:39:42

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 4'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 5'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 6'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:20:54', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47'	System	08 Sep 2020 20:22:05
User entered 'No interference with activity (1)'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:21:01', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47'	System	08 Sep 2020 20:22:05
User entered 'Some interference with activity (2)'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:21:08', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47'	System	08 Sep 2020 20:22:05
User entered 'No interference with activity (1)'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:21:15', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47'	System	08 Sep 2020 20:22:05
User entered 'No interference with activity (1)'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:21:20', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47' User entered 'None (0)'	System	08 Sep 2020 20:22:05
	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:21:35', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47'	System	08 Sep 2020 20:22:05
User entered 'Some interference with activity not requiring medical attention (2)'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:21:49', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47'	System	08 Sep 2020 20:22:05
User entered 'Yes (Y)'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-08T16:22:03', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ab97a841-5777-4890-a525-f1f0c48c1e47'	System	08 Sep 2020 20:22:05
User entered '08 Sep 2020 16:22'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 7'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:51:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75' User entered 'None (0)'	System	10 Sep 2020 12:52:38
	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:51:38', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75'	System	10 Sep 2020 12:52:38
User entered 'No interference with activity (1)'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:51:47', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75'	System	10 Sep 2020 12:52:38
User entered 'No interference with activity (1)'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:51:55', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75'	System	10 Sep 2020 12:52:38
User entered 'No interference with activity (1)'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:52:00', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75' User entered 'None (0)'	System	10 Sep 2020 12:52:38
	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:52:10', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75' User entered 'None (0)'	System	10 Sep 2020 12:52:38
	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:52:32', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75'	System	10 Sep 2020 12:52:38
User entered 'No (N)'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-10T08:52:36', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '085cfdcd-f270-4cba-b09b-7fc69c6cdd75' User entered '10 Sep 2020 08:52'	System	10 Sep 2020 12:52:38
	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	08 Sep 2020 16:46:52
User entered 'Day 8'	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:26:11', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '14414944-068a-4190-95bf-eb53e16e67f8'	System	11 Sep 2020 13:26:18
User entered 'None (1)'	System	11 Sep 2020 13:26:18

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:26:14', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '14414944-068a-4190-95bf-eb53e16e67f8'	System	11 Sep 2020 13:26:18
User entered '11 Sep 2020 09:26'	System	11 Sep 2020 13:26:18

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	08 Sep 2020 16:46:52
User entered 'Day 8'	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:26:27', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd22cf03d-7b97-4dd9-9886-627202078924'	System	11 Sep 2020 13:27:29
User entered 'Yes (Y)'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:27:08', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd22cf03d-7b97-4dd9-9886-627202078924'	System	11 Sep 2020 13:27:29
User entered '2'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:27:26', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'd22cf03d-7b97-4dd9-9886-627202078924'	System	11 Sep 2020 13:27:29
User entered '11 Sep 2020 09:27'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:46:52

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	10 Sep 2020 12:51:04
User entered 'Day 9'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:02:34', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b88f8527-1e2f-423e-a9bf-6cf04f41c609'	System	12 Sep 2020 13:02:58
User entered 'Yes (Y)'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:02:47', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b88f8527-1e2f-423e-a9bf-6cf04f41c609' User entered '2'	System	12 Sep 2020 13:02:58
	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:02:56', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b88f8527-1e2f-423e-a9bf-6cf04f41c609'	System	12 Sep 2020 13:02:58
User entered '12 Sep 2020 09:02'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	11 Sep 2020 13:27:29
User entered 'Day 10'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:18', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '36a40791-2583-4c0b-8c6a-a07f64648537' User entered 'Yes (Y)'	System	13 Sep 2020 13:37:33
	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '36a40791-2583-4c0b-8c6a-a07f64648537' User entered '2'	System	13 Sep 2020 13:37:33
	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:31', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '36a40791-2583-4c0b-8c6a-a07f64648537'	System	13 Sep 2020 13:37:33
User entered '13 Sep 2020 09:37'	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	12 Sep 2020 13:02:58
User entered 'Day 11'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T23:59:51', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '1c3e6677-7784-4a73-bd6c-e39a83dbe09b' User entered 'Yes (Y)'	System	14 Sep 2020 04:00:30
	System	14 Sep 2020 04:00:30

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:44:45

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:00:07', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '1c3e6677-7784-4a73-bd6c-e39a83dbe09b' User entered '2'	System	14 Sep 2020 04:00:30
	System	14 Sep 2020 04:00:30

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:00:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '1c3e6677-7784-4a73-bd6c-e39a83dbe09b' User entered '14 Sep 2020 00:00'	System	14 Sep 2020 04:00:30
	System	14 Sep 2020 04:00:30

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	13 Sep 2020 13:37:33
User entered 'Day 12'	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:44:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:50:34', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '3a597ad6-61dd-4a0a-a882-924f992e0723' User entered 'No (N)'	System	15 Sep 2020 13:50:49
	System	15 Sep 2020 13:50:49

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:50:45', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '3a597ad6-61dd-4a0a-a882-924f992e0723'	System	15 Sep 2020 13:50:49
User entered '15 Sep 2020 09:50'	System	15 Sep 2020 13:50:49

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	08 Sep 2020 20:22:05
User entered 'Day 8'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:27:39', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'c3a2355e-99f9-49fd-a758-c3901db064f3'	System	11 Sep 2020 13:27:47
User entered 'No interference with activity (1)'	System	11 Sep 2020 13:27:47

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:27:44', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'c3a2355e-99f9-49fd-a758-c3901db064f3'	System	11 Sep 2020 13:27:47
User entered '11 Sep 2020 09:27'	System	11 Sep 2020 13:27:47

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	10 Sep 2020 12:52:38
User entered 'Day 9'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:03:08', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f34b8ae9-164f-4f22-be60-43eef1691d85'	System	12 Sep 2020 13:03:18
User entered 'Some interference with activity (2)'	System	12 Sep 2020 13:03:18

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:03:15', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'f34b8ae9-164f-4f22-be60-43eef1691d85'	System	12 Sep 2020 13:03:18
User entered '12 Sep 2020 09:03'	System	12 Sep 2020 13:03:18

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	11 Sep 2020 13:27:47
User entered 'Day 10'	System	11 Sep 2020 13:27:47

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:44:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:39', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5f2f067a-eda1-453c-90eb-da610928e36a'	System	13 Sep 2020 13:37:44
User entered 'No interference with activity (1)'	System	13 Sep 2020 13:37:44

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:42', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5f2f067a-eda1-453c-90eb-da610928e36a' User entered '13 Sep 2020 09:37'	System	13 Sep 2020 13:37:44
	System	13 Sep 2020 13:37:44

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:27:47

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:27:47

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	12 Sep 2020 13:03:18
User entered 'Day 11'	System	12 Sep 2020 13:03:18

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:00:40', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a0ae444a-5d50-4908-a55b-587cdfc88564'	System	14 Sep 2020 04:00:57
User entered 'Some interference with activity (2)'	System	14 Sep 2020 04:00:57

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:00:53', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a0ae444a-5d50-4908-a55b-587cdfc88564'	System	14 Sep 2020 04:00:57
User entered '14 Sep 2020 00:00'	System	14 Sep 2020 04:00:57

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:03:18

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:03:18

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	13 Sep 2020 13:37:44
User entered 'Day 12'	System	13 Sep 2020 13:37:44

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:50:54', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '18e53eeb-235d-4160-92c1-88b70d8e55d7' User entered 'None (0)'	System	15 Sep 2020 13:51:11
	System	15 Sep 2020 13:51:11

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:51:01', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '18e53eeb-235d-4160-92c1-88b70d8e55d7'	System	15 Sep 2020 13:51:11
User entered '15 Sep 2020 09:51'	System	15 Sep 2020 13:51:11

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 13:37:44

US3902030

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 13:37:44

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	08 Sep 2020 20:22:05
User entered 'Day 8'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:28:05', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '1573ba41-2a78-4925-a847-19c4e97498d0'	System	11 Sep 2020 13:28:22
User entered 'No interference with activity (1)'	System	11 Sep 2020 13:28:22

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:28:19', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '1573ba41-2a78-4925-a847-19c4e97498d0'	System	11 Sep 2020 13:28:22
User entered '11 Sep 2020 09:28'	System	11 Sep 2020 13:28:22

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	10 Sep 2020 12:52:38
User entered 'Day 9'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:03:29', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a954aa70-a8f0-4a02-b76e-5665c79151ce' User entered 'No interference with activity (1)'	System	12 Sep 2020 13:03:44
	System	12 Sep 2020 13:03:44

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:03:42', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'a954aa70-a8f0-4a02-b76e-5665c79151ce' User entered '12 Sep 2020 09:03'	System	12 Sep 2020 13:03:44
	System	12 Sep 2020 13:03:44

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	11 Sep 2020 13:28:22
User entered 'Day 10'	System	11 Sep 2020 13:28:22

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:48', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '90f42383-f0cd-4aa7-b9a0-059cfa5ca7a0'	System	13 Sep 2020 13:37:55
User entered 'No interference with activity (1)'	System	13 Sep 2020 13:37:55

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:50', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '90f42383-f0cd-4aa7-b9a0-059cfa5ca7a0'	System	13 Sep 2020 13:37:55
User entered '13 Sep 2020 09:37'	System	13 Sep 2020 13:37:55

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:28:22

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:28:22

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	12 Sep 2020 13:03:44
User entered 'Day 11'	System	12 Sep 2020 13:03:44

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:01:11', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '926a8f71-d848-4737-a82b-e1feb5390d20'	System	14 Sep 2020 04:01:18
User entered 'Some interference with activity (2)'	System	14 Sep 2020 04:01:18

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:01:16', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '926a8f71-d848-4737-a82b-e1feb5390d20'	System	14 Sep 2020 04:01:18
User entered '14 Sep 2020 00:01'	System	14 Sep 2020 04:01:18

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:03:44

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:03:44

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	13 Sep 2020 13:37:55
User entered 'Day 12'	System	13 Sep 2020 13:37:55

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:51:19', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '625919d7-d44c-4f74-9f3c-c347404b51d8' User entered 'None (0)'	System	15 Sep 2020 13:51:27
	System	15 Sep 2020 13:51:27

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:51:24', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '625919d7-d44c-4f74-9f3c-c347404b51d8' User entered '15 Sep 2020 09:51'	System	15 Sep 2020 13:51:27
	System	15 Sep 2020 13:51:27

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 13:37:55

US3902030

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 13:37:55

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	08 Sep 2020 20:22:05
User entered 'Day 8'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:28:42', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '9d45ed91-16a9-44e5-9a14-41acd07fc485'	System	11 Sep 2020 13:29:05
User entered 'No interference with activity (1)'	System	11 Sep 2020 13:29:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:28:57', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '9d45ed91-16a9-44e5-9a14-41acd07fc485'	System	11 Sep 2020 13:29:05
User entered '11 Sep 2020 09:28'	System	11 Sep 2020 13:29:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:22:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	10 Sep 2020 12:52:38
User entered 'Day 9'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:03:50', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '8097b457-2b9d-4601-b130-c5d228f71931'	System	12 Sep 2020 13:03:56
User entered 'Some interference with activity (2)'	System	12 Sep 2020 13:03:56

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:03:54', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '8097b457-2b9d-4601-b130-c5d228f71931' User entered '12 Sep 2020 09:03'	System	12 Sep 2020 13:03:56
	System	12 Sep 2020 13:03:56

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:52:38

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	11 Sep 2020 13:29:05
User entered 'Day 10'	System	11 Sep 2020 13:29:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:37:59', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '6d94f281-d621-4b97-83af-38be577da004'	System	13 Sep 2020 13:38:06
User entered 'No interference with activity (1)'	System	13 Sep 2020 13:38:06

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:38:02', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '6d94f281-d621-4b97-83af-38be577da004'	System	13 Sep 2020 13:38:06
User entered '13 Sep 2020 09:38'	System	13 Sep 2020 13:38:06

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:29:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:29:05

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	12 Sep 2020 13:03:56
User entered 'Day 11'	System	12 Sep 2020 13:03:56

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:01:32', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '84406364-ccea-4590-ab62-15fbc4010261' User entered 'Some interference with activity (2)'	System	14 Sep 2020 04:01:39
	System	14 Sep 2020 04:01:39

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:01:36', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '84406364-ccea-4590-ab62-15fbc4010261' User entered '14 Sep 2020 00:01'	System	14 Sep 2020 04:01:39
	System	14 Sep 2020 04:01:39

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:03:56

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:03:56

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	13 Sep 2020 13:38:06
User entered 'Day 12'	System	13 Sep 2020 13:38:06

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:51:34', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '33403a19-e854-4e7b-955c-5c20252c68e5' User entered 'None (0)'	System	15 Sep 2020 13:51:42
	System	15 Sep 2020 13:51:42

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:51:39', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '33403a19-e854-4e7b-955c-5c20252c68e5' User entered '15 Sep 2020 09:51'	System	15 Sep 2020 13:51:42
	System	15 Sep 2020 13:51:42

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 13:38:06

US3902030

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 13:38:06

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	08 Sep 2020 16:45:46
User entered 'Day 8'	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:29:09', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '149392be-cb7d-4e90-bd7d-1077fc0052d4'	System	11 Sep 2020 13:29:23
User entered 'No (N)'	System	11 Sep 2020 13:29:23

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-11T09:29:15', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '149392be-cb7d-4e90-bd7d-1077fc0052d4'	System	11 Sep 2020 13:29:23
User entered '11 Sep 2020 09:29'	System	11 Sep 2020 13:29:23

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:45:46

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	10 Sep 2020 12:51:04
User entered 'Day 9'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:04:04', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '92416f31-84d1-4766-84e3-012bd24722e0' User entered 'No (N)'	System	12 Sep 2020 13:04:10
	System	12 Sep 2020 13:04:10

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-12T09:04:08', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '92416f31-84d1-4766-84e3-012bd24722e0' User entered '12 Sep 2020 09:04'	System	12 Sep 2020 13:04:10
	System	12 Sep 2020 13:04:10

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:51:04

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	11 Sep 2020 13:27:29
User entered 'Day 10'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:38:08', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ca682236-264a-4864-9745-d33da7d6f0c1' User entered 'No (N)'	System	13 Sep 2020 13:38:13
	System	13 Sep 2020 13:38:13

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-13T09:38:11', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ca682236-264a-4864-9745-d33da7d6f0c1' User entered '13 Sep 2020 09:38'	System	13 Sep 2020 13:38:13
	System	13 Sep 2020 13:38:13

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:27:29

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	12 Sep 2020 13:02:58
User entered 'Day 11'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:01:48', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '516285df-07b7-4218-9130-8030e0778d05'	System	14 Sep 2020 04:01:57
User entered 'No (N)'	System	14 Sep 2020 04:01:57

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-14T00:01:54', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '516285df-07b7-4218-9130-8030e0778d05'	System	14 Sep 2020 04:01:57
User entered '14 Sep 2020 00:01'	System	14 Sep 2020 04:01:57

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 13:02:58

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	13 Sep 2020 13:37:33
User entered 'Day 12'	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:44:45

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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:51:46', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '32877af7-9407-4f93-b2cb-ee363774271a' User entered 'No (N)'	System	15 Sep 2020 13:51:54
	System	15 Sep 2020 13:51:54

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-09-15T09:51:52', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '32877af7-9407-4f93-b2cb-ee363774271a' User entered '15 Sep 2020 09:51'	System	15 Sep 2020 13:51:54
	System	15 Sep 2020 13:51:54

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 13:37:33

US3902030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:44:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 13:37:33

US3902030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:05:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:18:33

US3902030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:05:42
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 18:18:33

US3902030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:05:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 18:18:33

US3902030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:05:42
User entered 'hives are going away, no other changes'	(b) (4), (b) (6)	10 Sep 2020 18:18:33

US3902030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 17:05:51
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:34:41

US3902030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '1'	System	16 Sep 2020 15:34:41

US3902030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:15:00

US3902030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:28
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 17:15:46
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	25 Sep 2020 17:15:46
User entered '19 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:15:46
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 17:15:00
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:15:00

US3902030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 17:15:00

US3902030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:15:00

US3902030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:15:56

US3902030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'I'	System	25 Sep 2020 17:15:56

US3902030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:24:25

US3902030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:44
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 18:24:25

US3902030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 18:24:25

US3902030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:44
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:25

US3902030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:22:53
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:47:22

US3902030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'I'	System	12 Oct 2020 17:47:22

US3902030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:53
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:47:50

US3902030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:59:32
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:25:37
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	06 Nov 2020 23:29:37
DataPoint Un-verified.	(b) (4)	
	Taylor Atkinson (b) (4)	06 Nov 2020 23:29:30
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Taylor Atkinson (b) (4)	06 Nov 2020 23:29:30
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 01-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:21:22
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:53
User entered '1 Oct 2020'	Bram Swarr (b) (4)	12 Oct 2020 17:47:50

US3902030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:53
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	12 Oct 2020 17:47:50

US3902030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'VISIT2'	System	12 Oct 2020 17:47:50

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Pre-Dose (PREDOSE)'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered '1 Oct 2020'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered '10:10'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '1 Oct 2020 10:10'	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered '97.6' F	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered '80'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'bpm'	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered '14'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'breaths/min'	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered '103'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'mmHg'	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered '65'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'mmHg'	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Post-Dose (POSTDOSE)'	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per CDM: Were vital signs assessed?' is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate Thank you..' (Site from DM). Query 'Per CDM: Were vital signs assessed?' is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate Thank you..' answered with 'Subject was not dosed. Please see dosing discontinuation page' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 23:38:21
User opened query 'Per CDM: Were vital signs assessed?' is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate Thank you..' (Site from DM). DataPoint Verified.	Taylor Atkinson (b) (4)	13 Nov 2020 23:38:31
User opened query 'Per CDM: Were vital signs assessed?' is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate Thank you..' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 15:23:02
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:36:31
	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:31
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:49:23

US3902030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:52
User entered 'No (N)'	Bram Swarr (b) (4)	12 Oct 2020 17:49:36

US3902030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:52
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:49:36

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:38:56
User entered 'No (N)'	Bram Swarr (b) (4)	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per CDM: Reason mentioned as 'Physician withheld dose due to Adverse Event', however there is no appropriate event is reported on 'Adverse event' form. Please reconcile and update the data as appropriate, thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:07:33
Query 'Per CDM: Reason mentioned as 'Physician withheld dose due to Adverse Event', however there is no appropriate event is reported on 'Adverse event' form. Please reconcile and update the data as appropriate, thank you. ' answered with 'Linked to AE' (Site from DM).	Taylor Atkinson (b) (4)	22 Oct 2020 22:54:24
User opened query 'Per CDM: Reason mentioned as 'Physician withheld dose due to Adverse Event', however there is no appropriate event is reported on 'Adverse event' form. Please reconcile and update the data as appropriate, thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 05:12:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:38:56
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Bram Swarr (b) (4)	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

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)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:48:20
User closed query 'please complete data field. PI decision' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 14:36:20
Query 'please complete data field. PI decision' answered with 'Completed' (Site from CRA).	Taylor Atkinson (b) (4)	22 Oct 2020 22:54:16
DataPoint Un-verified.	(b) (4)	
	Taylor Atkinson (b) (4)	22 Oct 2020 22:54:01
User entered 'Physician decided based on adverse reaction to first vaccination' reason for change: Data Entry Error	(b) (4)	
	Taylor Atkinson (b) (4)	22 Oct 2020 22:54:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:38:56
User opened query 'please complete data field. PI decision' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:38:44
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:38:56
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:38:56
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:38:56
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:38:56
User entered empty.	System	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:44:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:51:29

US3902030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:31
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:51:48

US3902030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:31
User entered '1 Oct 2020'	Bram Swarr (b) (4)	12 Oct 2020 17:51:48

US3902030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:31
User entered '11:52'	Bram Swarr (b) (4)	12 Oct 2020 17:51:48

US3902030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '1 Oct 2020 11:52'	System	12 Oct 2020 17:51:48

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:44:45

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:44
User entered '1 Oct 2020'	Bram Swarr (b) (4)	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bram Swarr (b) (4)	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:44
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:44
User entered '11:53'	Bram Swarr (b) (4)	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '1 Oct 2020 11:53'	System	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bram Swarr (b) (4)	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:44
User entered 'No (N)'	Bram Swarr (b) (4)	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:44
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	12 Oct 2020 17:52:08

US3902030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:39:58
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:52:33

US3902030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '1'	System	12 Oct 2020 17:52:33

US3902030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:23:17
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:53:55

US3902030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:23:17
User entered '09 Oct 2020' reason for change: Data Entry Error	Bram Swarr (b) (4)	12 Oct 2020 18:11:09
User entered '1 Oct 2020'	Bram Swarr (b) (4)	12 Oct 2020 17:53:55

US3902030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:23:17
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	12 Oct 2020 17:53:55

US3902030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:23:17
User entered empty.	Bram Swarr (b) (4)	12 Oct 2020 17:53:55

US3902030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:23:29
User entered 'Yes (Y)'	Bram Swarr (b) (4)	12 Oct 2020 17:54:00

US3902030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'I'	System	12 Oct 2020 17:54:00

US3902030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:36:59
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	18 Oct 2020 14:16:30

US3902030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:36:59
User entered '18 Oct 2020'	Taylor Atkinson (b) (4)	18 Oct 2020 14:16:30

US3902030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:36:59
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	18 Oct 2020 14:16:30

US3902030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:36:59
User entered empty.	Taylor Atkinson (b) (4)	18 Oct 2020 14:16:30

US3902030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:07
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	18 Oct 2020 14:16:21

US3902030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'I'	System	18 Oct 2020 14:16:21

US3902030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:14
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:04

US3902030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:14
User entered '22 Oct 2020'	Bram Swarr (b) (4)	28 Oct 2020 16:58:04

US3902030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:14
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:04

US3902030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:14
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:04

US3902030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:22
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:08

US3902030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'I'	System	28 Oct 2020 16:58:08

US3902030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:54
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:28

US3902030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:54
User entered '26 Oct 2020'	Bram Swarr (b) (4)	28 Oct 2020 16:58:28

US3902030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:37:54
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:28

US3902030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'VISIT3'	System	28 Oct 2020 16:58:28

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:45
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered empty.	System	28 Oct 2020 16:58:40

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07

US3902030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07

US3902030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:39
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:43

US3902030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:39
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 16:58:43

US3902030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:55
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 16:58:57

US3902030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:55
User entered '26 Oct 2020'	Bram Swarr (b) (4)	28 Oct 2020 16:58:57

US3902030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:38:55
User entered '10:50'	Bram Swarr (b) (4)	28 Oct 2020 16:58:57

US3902030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '26 Oct 2020 10:50'	System	28 Oct 2020 16:58:57

US3902030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:39:03
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 16:59:07

US3902030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered '1'	System	28 Oct 2020 16:59:07

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 64'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-04T08:36:15', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '2cd70425-431a-41a1-9616-5d6e5ec45e49'	System	04 Nov 2020 13:36:59
User entered 'No (N)'	System	04 Nov 2020 13:36:59

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-04T08:36:27', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '2cd70425-431a-41a1-9616-5d6e5ec45e49'	System	04 Nov 2020 13:36:59
User entered 'No (N)'	System	04 Nov 2020 13:36:59

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-04T08:36:54', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '2cd70425-431a-41a1-9616-5d6e5ec45e49' User entered '04 Nov 2020 08:36:54'	System	04 Nov 2020 13:36:59
	System	04 Nov 2020 13:36:59

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 71'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-10T08:24:09', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '4797f7f1-0dd8-40bf-9fff-4a4bb3c2c538'	System	10 Nov 2020 13:24:37
User entered 'No (N)'	System	10 Nov 2020 13:24:37

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-10T08:24:21', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '4797f7f1-0dd8-40bf-9fff-4a4bb3c2c538'	System	10 Nov 2020 13:24:37
User entered 'No (N)'	System	10 Nov 2020 13:24:37

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-10T08:24:35', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '4797f7f1-0dd8-40bf-9fff-4a4bb3c2c538'	System	10 Nov 2020 13:24:37
User entered '10 Nov 2020 08:24:35'	System	10 Nov 2020 13:24:37

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
Data entry locked.	System	03 Sep 2020 21:38:23
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:08:39
User closed query 'please confirm this entry covers D75' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 15:33:43
Query 'please confirm this entry covers D75' answered with 'According to the Diary, Day 78's window was between 18Nov and 21Nov2020. With the new diary conversion, even though the subject did their diary on the 21Nov2020, it showed up for Day 82 instead and looked like a missed entry' (Site from CRA).	Taylor Atkinson (b) (4)	24 Nov 2020 12:06:55
User opened query 'please confirm this entry covers D75' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 19:04:50
Data entry locked.	System	03 Sep 2020 21:38:23
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13
Data entry locked.	System	03 Sep 2020 21:38:23
User entered 'Day 78'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13
Data entry locked.	System	03 Sep 2020 21:38:23
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 21:38:23

US3902030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:00:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:36:13
Data entry locked.	System	03 Sep 2020 21:38:23
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 21:38:23

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-21T08:06:13', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'baef076d-007e-4bdc-ba7f-0f2d26caeab2' User entered 'No (N)'	System	21 Nov 2020 13:06:40
	System	21 Nov 2020 13:06:40

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-21T08:06:20', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'baef076d-007e-4bdc-ba7f-0f2d26caeab2'	System	21 Nov 2020 13:06:40
User entered 'No (N)'	System	21 Nov 2020 13:06:40

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-11-21T08:06:37', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'baef076d-007e-4bdc-ba7f-0f2d26caeab2' User entered '21 Nov 2020 08:06:37'	System	21 Nov 2020 13:06:40
	System	21 Nov 2020 13:06:40

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-02T11:59:54', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '213d1858-a1c8-4f65-a4d4-6299f3c359d2' User entered 'Yes (Y)'	System	02 Dec 2020 17:00:41
	System	02 Dec 2020 17:00:41

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-02T12:00:00', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '213d1858-a1c8-4f65-a4d4-6299f3c359d2'	System	02 Dec 2020 17:00:41
User entered 'No (N)'	System	02 Dec 2020 17:00:41

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-02T12:00:06', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '213d1858-a1c8-4f65-a4d4-6299f3c359d2' User entered 'No (N)'	System	02 Dec 2020 17:00:41
	System	02 Dec 2020 17:00:41

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-02T12:00:28', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '213d1858-a1c8-4f65-a4d4-6299f3c359d2' User entered 'No (N)'	System	02 Dec 2020 17:00:41
	System	02 Dec 2020 17:00:41

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-02T12:00:34', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '213d1858-a1c8-4f65-a4d4-6299f3c359d2' User entered '02 Dec 2020 12:00:34'	System	02 Dec 2020 17:00:41
	System	02 Dec 2020 17:00:41

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-05T08:19:50', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '8f12954a-e91c-49c2-933c-8041ed5a1005'	System	05 Dec 2020 13:20:09
User entered 'No (N)'	System	05 Dec 2020 13:20:09

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-05T08:19:55', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '8f12954a-e91c-49c2-933c-8041ed5a1005'	System	05 Dec 2020 13:20:09
User entered 'No (N)'	System	05 Dec 2020 13:20:09

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-05T08:20:06', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '8f12954a-e91c-49c2-933c-8041ed5a1005'	System	05 Dec 2020 13:20:09
User entered '05 Dec 2020 08:20:06'	System	05 Dec 2020 13:20:09

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-16T12:09:38', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ebb6018a-bc45-4f76-b84d-620a8cf06d16'	System	16 Dec 2020 17:09:51
User entered 'No (N)'	System	16 Dec 2020 17:09:51

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-16T12:09:41', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ebb6018a-bc45-4f76-b84d-620a8cf06d16'	System	16 Dec 2020 17:09:51
User entered 'No (N)'	System	16 Dec 2020 17:09:51

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-16T12:09:45', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'ebb6018a-bc45-4f76-b84d-620a8cf06d16' User entered '16 Dec 2020 12:09:45'	System	16 Dec 2020 17:09:51
	System	16 Dec 2020 17:09:51

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-19T07:26:09', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '064b875c-e72a-461a-b834-a1e878d60b41' User entered 'No (N)'	System	19 Dec 2020 12:26:43
	System	19 Dec 2020 12:26:43

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-19T07:26:20', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '064b875c-e72a-461a-b834-a1e878d60b41' User entered 'No (N)'	System	19 Dec 2020 12:26:43
	System	19 Dec 2020 12:26:43

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-19T07:26:39', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '064b875c-e72a-461a-b834-a1e878d60b41' User entered '19 Dec 2020 07:26:39'	System	19 Dec 2020 12:26:43
	System	19 Dec 2020 12:26:43

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-28T12:01:04', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '50aca628-801e-457e-add2-3c0fb379da77'	System	28 Dec 2020 17:01:27
User entered 'No (N)'	System	28 Dec 2020 17:01:27

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-28T12:01:13', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '50aca628-801e-457e-add2-3c0fb379da77'	System	28 Dec 2020 17:01:27
User entered 'No (N)'	System	28 Dec 2020 17:01:27

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2020-12-28T12:01:18', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '50aca628-801e-457e-add2-3c0fb379da77' User entered '28 Dec 2020 12:01:18'	System	28 Dec 2020 17:01:27
	System	28 Dec 2020 17:01:27

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-02T10:30:32', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b77c1eb8-544e-4655-9d3d-2d3a787ca170'	System	02 Jan 2021 15:30:51
User entered 'No (N)'	System	02 Jan 2021 15:30:51

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-02T10:30:42', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b77c1eb8-544e-4655-9d3d-2d3a787ca170'	System	02 Jan 2021 15:30:51
User entered 'No (N)'	System	02 Jan 2021 15:30:51

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-02T10:30:48', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: 'b77c1eb8-544e-4655-9d3d-2d3a787ca170'	System	02 Jan 2021 15:30:51
User entered '02 Jan 2021 10:30:48'	System	02 Jan 2021 15:30:51

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-12T19:59:02', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5dd0920b-236e-49ab-9207-0f9a1d8ba2d7'	System	13 Jan 2021 00:59:17
User entered 'No (N)'	System	13 Jan 2021 00:59:17

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-12T19:59:08', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5dd0920b-236e-49ab-9207-0f9a1d8ba2d7'	System	13 Jan 2021 00:59:17
User entered 'No (N)'	System	13 Jan 2021 00:59:17

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-12T19:59:14', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '5dd0920b-236e-49ab-9207-0f9a1d8ba2d7'	System	13 Jan 2021 00:59:17
User entered '12 Jan 2021 19:59:14'	System	13 Jan 2021 00:59:17

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-16T10:32:45', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f7edfbf-8703-4550-8429-2007957899f2'	System	16 Jan 2021 15:32:56
User entered 'No (N)'	System	16 Jan 2021 15:32:56

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

Have you been exposed to someone with 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 (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-16T10:32:47', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f7edfbf-8703-4550-8429-2007957899f2'	System	16 Jan 2021 15:32:56
User entered 'No (N)'	System	16 Jan 2021 15:32:56

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2A95200-731F-4B3A-8AAF-9E9957126DA7)', Time: '2021-01-16T10:32:52', User OID: 'PatientReportedOutcome (US3902030)', ODM File OID: '0f7edfbf-8703-4550-8429-2007957899f2' User entered '16 Jan 2021 10:32:52'	System	16 Jan 2021 15:32:56
	System	16 Jan 2021 15:32:56

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:36:13

US3902030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:44:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:36:13
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:36:13

US3902030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:00:22
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Nov 2020 19:07:35

US3902030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:00:22
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered '24 Nov 2020'	Bram Swarr (b) (4)	25 Nov 2020 19:07:35

US3902030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:00:22
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	25 Nov 2020 19:07:35

US3902030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:00:22
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered empty.	Bram Swarr (b) (4)	25 Nov 2020 19:07:35

US3902030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:00:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Yes (Y)'	Bram Swarr (b) (4)	25 Nov 2020 19:07:44

US3902030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:19:07
User entered 'I'	System	25 Nov 2020 19:07:44

US3902030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:32:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 16:38:29

US3902030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:32:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered '28 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 16:38:29

US3902030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:32:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Dec 2020 16:38:29

US3902030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:32:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 16:38:29

US3902030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:32:36
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 20:29:51

US3902030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User entered 'I'	System	28 Dec 2020 20:29:51

US3902030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:08
User entered 'Yes (Y)'	Bram Swarr (b) (4)	26 Feb 2021 19:23:27

US3902030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:08
User entered '26 Jan 2021'	Bram Swarr (b) (4)	26 Feb 2021 19:23:27

US3902030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:08
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	26 Feb 2021 19:23:27

US3902030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:08
User entered empty.	Bram Swarr (b) (4)	26 Feb 2021 19:23:27

US3902030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:23
User entered 'Yes (Y)'	Bram Swarr (b) (4)	26 Feb 2021 19:23:35

US3902030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User entered 'I'	System	26 Feb 2021 19:23:35

US3902030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:40
User entered 'Yes (Y)'	Bram Swarr (b) (4)	26 Feb 2021 19:24:43

US3902030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:40
User entered '25 Feb 2021'	Bram Swarr (b) (4)	26 Feb 2021 19:24:43

US3902030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:40
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	26 Feb 2021 19:24:43

US3902030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:40
User entered empty.	Bram Swarr (b) (4)	26 Feb 2021 19:24:43

US3902030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:32:48
User entered 'Yes (Y)'	Bram Swarr (b) (4)	26 Feb 2021 19:25:01

US3902030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:35
User entered 'I'	System	26 Feb 2021 19:25:01

US3902030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User closed query 'please enter vital signs. per source 98.3, 152/83, 72, 16' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:38:58
Query 'please enter vital signs. per source 98.3, 152/83, 72, 16' answered with 'entered' (Site from CRA).	Taylor Atkinson (b) (4) (b) (4)	01 Apr 2021 12:53:07
User opened query 'please enter vital signs. per source 98.3, 152/83, 72, 16' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 16:34:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:33:22
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 18:43:28

US3902030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:33:22
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered '19 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 18:43:28

US3902030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:33:22
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 18:43:28

US3902030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'VISIT4'	System	24 Mar 2021 18:43:28

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered '19 Mar 2021'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered '10:04'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User entered '19 Mar 2021 10:04'	System	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered '98.3' F	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered 'Oral (Oral)'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered empty.	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered '72'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User entered 'bpm'	System	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered '16'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User entered 'breaths/min'	System	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered '152'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User entered 'mmHg'	System	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:39:08
User entered '83'	Taylor Atkinson (b) (4)	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29
User entered 'mmHg'	System	01 Apr 2021 12:29:43

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29

US3902030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:44:45

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:30:29

US3902030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:50:19
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 18:43:46

US3902030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:44:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:50:19
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 18:43:46

US3902030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:35:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 18:44:05

US3902030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:35:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered '19 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 18:44:05

US3902030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:35:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered '10:31'	(b) (4), (b) (6)	24 Mar 2021 18:44:05

US3902030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered '19 Mar 2021 10:31'	System	24 Mar 2021 18:44:05

US3902030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:36:11
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 18:44:12

US3902030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:29:44
User entered 'I'	System	24 Mar 2021 18:44:12

US3902030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:32:52

US3902030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
User entered '26 Apr 2021'	Bram Swarr (b) (4)	28 Apr 2021 17:32:52

US3902030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:32:52

US3902030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:44:45

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
User entered empty.	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:32:52

US3902030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:57

US3902030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:44:45

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:32:57

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:05
User entered 'Yes (Y)'	Bram Swarr (b) (4)	26 Feb 2021 19:22:52

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:05
User entered '1 Feb 2021'	Bram Swarr (b) (4)	26 Feb 2021 19:22:52

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:05
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	26 Feb 2021 19:22:52

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:44:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User entered 'UNBLND_DECIDE'	System	26 Feb 2021 19:22:52

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:14
User entered '1 Feb 2021'	Bram Swarr (b) (4)	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:34:04

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:14
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:34:04

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:14
User entered '1 Feb 2021'	Bram Swarr (b) (4)	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:14
User entered 'mRNA-1273 (mRNA-1273)'	Bram Swarr (b) (4)	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:14
User entered 'mRNA-1273 (mRNA-1273)'	Bram Swarr (b) (4)	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:14
User entered 'Not Administered (NA)'	Bram Swarr (b) (4)	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:14
User entered 'No (N)'	Bram Swarr (b) (4)	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User entered empty.	System	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:44:45

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User entered empty.	System	04 Feb 2021 14:32:53

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:27
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Feb 2021 14:33:10

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:27
User entered '1 Feb 2021'	Bram Swarr (b) (4)	04 Feb 2021 14:33:10

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:27
User entered '14:58'	Bram Swarr (b) (4)	04 Feb 2021 14:33:10

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:44:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User entered '1 Feb 2021 14:58'	System	04 Feb 2021 14:33:10

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:44:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:33
User entered 'Yes (Y)'	Bram Swarr (b) (4)	04 Feb 2021 14:33:31

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:44:45

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:33
User entered '1 Feb 2021'	Bram Swarr (b) (4)	04 Feb 2021 14:33:31

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:44:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:33
User entered '14:59'	Bram Swarr (b) (4)	04 Feb 2021 14:33:31

US3902030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:44:45

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:50:05
User entered '1 Feb 2021 14:59'	System	04 Feb 2021 14:33:31

US3902030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:44:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:38:01
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE, INJECTION SITE REDNESS, JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 8; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 11:00:38
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE, INJECTION SITE REDNESS, JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 8; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'AE source pages created, will enter upon PI review' (Site from DM).	Bram Swarr (b) (4)	08 Mar 2021 16:07:41
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE, INJECTION SITE REDNESS, JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 8; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 03:19:25
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:14
User entered 'Yes (Y)'	Taylor Atkinson (b) (4) (b) (4)	16 Sep 2020 15:34:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	14 Oct 2020 18:24:15
DataPoint Verified.	Coder Import (b) (4)	16 Sep 2020 15:38:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 15:38:45
Data point term sent to Coder	(b) (4)	
User entered 'Hives'	System	16 Sep 2020 15:37:22
	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:39:39
User closed query 'please confirm if answer should be no. Subject had USV at site on 08Sep2020 to assess hives. Please reconcile.' (Site from CRA). Query 'please confirm if answer should be no. Subject had USV at site on 08Sep2020 to assess hives. Please reconcile.' answered with 'Corrected' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:39:36
DataPoint Un-verified.	Taylor Atkinson (b) (4)	22 Oct 2020 22:54:49
	(b) (4)	
	Taylor Atkinson (b) (4)	22 Oct 2020 22:54:44
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	22 Oct 2020 22:54:44
	(b) (4)	
User opened query 'please confirm if answer should be no. Subject had USV at site on 08Sep2020 to assess hives. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:28:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
	(b) (4)	
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	14 Oct 2020 18:24:15
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 07:11:56
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).		
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	12 Oct 2020 18:03:08
User entered 'No (N)' reason for change: Data Entry Error	Bram Swarr (b) (4)	12 Oct 2020 18:00:59
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 20:16:17
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '05 Sep 2020'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 15:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:58
	(b) (4)	
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	14 Oct 2020 18:24:15
DataPoint Verified.	System	01 Oct 2020 17:18:22
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	Taylor Atkinson (b) (4)	01 Oct 2020 17:18:22
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 17:17:58
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:58
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	16 Sep 2020 15:36:22
User entered empty.	Taylor Atkinson (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 15:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:37:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 15:37:03
User entered 'Related (RELATED)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:37:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:36:22
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:37:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 15:37:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:37:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:36:22
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	25 Nov 2020 01:56:38
User closed query 'Per CDM Re-Query: previous response of Hives is noted however updates have not been made to the other adverse events. Please make those updates.' (Site from DM).		
Query 'Per CDM Re-Query: previous response of Hives is noted however updates have not been made to the other adverse events. Please make those updates.' answered with 'Updated to reflect this' (Site from DM).	Taylor Atkinson (b) (4)	24 Nov 2020 17:52:27
	(b) (4), (b) (6)	18 Nov 2020 16:58:26
User opened query 'Per CDM Re-Query: previous response of Hives is noted however updates have not been made to the other adverse events. Please make those updates.' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
	(b) (4), (b) (6)	13 Oct 2020 14:59:59
User closed query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate.' (Site from DM).		
Query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate.' answered with 'Per PI, the AE ultimately determining IP withdrawal is Hives.' (Site from DM).	Bram Swarr (b) (4)	12 Oct 2020 18:05:35
	(b) (4), (b) (6)	08 Oct 2020 14:09:32
User opened query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate.' (Site from DM).		
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:37:03

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 15:37:03
User entered 'None (NONE)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:37:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:36:22
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

None

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 15:37:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 15:36:22
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '1' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:37:03
	(b) (4)	
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:37:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 15:37:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:37:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:36:22
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:36:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Sep 2020 15:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 22:54:44
User entered '0'	System	16 Sep 2020 15:36:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	14 Oct 2020 18:24:15
DataPoint Verified.	Coder Import (b) (4)	02 Oct 2020 09:03:38
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: Pain in extremity, LLT: Hand pain - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 09:03:38
Data point term sent to Coder	System	01 Oct 2020 17:16:36
User entered 'Sore Hands'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '5 Sep 2020'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 17:15:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 17:16:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 17:16:05
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	01 Oct 2020 17:16:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 17:15:59
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '23 Sep 2020'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 17:15:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Related (RELATED)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Not Related (NOT RELATED)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	24 Nov 2020 17:52:03
DataPoint Un-verified.	(b) (4)	
	Taylor Atkinson (b) (4)	24 Nov 2020 17:51:26
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	24 Nov 2020 17:51:26
	(b) (4)	
User closed query 'Per CDM: Previous query response indicates, "Per PI, the AE ultimately determining IP withdrawal is Hives," however, Action taken with investigational product is 'Investigational Product Withdrawn'. Only the AE that led to the drug being withdrawn should have this recorded. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:10:45
Query 'Per CDM: Previous query response indicates, "Per PI, the AE ultimately determining IP withdrawal is Hives," however, Action taken with investigational product is 'Investigational Product Withdrawn'. Only the AE that led to the drug being withdrawn should have this recorded. Please clarify and update as appropriate.' answered with 'All 3 AEs started at the same time and were related, so they all led to PI decision' (Site from DM).	Taylor Atkinson (b) (4)	23 Oct 2020 18:57:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
	(b) (4), (b) (6)	
User opened query 'Per CDM: Previous query response indicates, "Per PI, the AE ultimately determining IP withdrawal is Hives," however, Action taken with investigational product is 'Investigational Product Withdrawn'. Only the AE that led to the drug being withdrawn should have this recorded. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:01:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:01:32
Query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate. ' answered with 'Per PI, the AE ultimately determining IP withdrawal is Hives.' (Site from DM).	Bram Swarr (b) (4)	12 Oct 2020 18:09:41
User opened query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:10:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Taylor Atkinson (b) (4) (b) (4)	01 Oct 2020 17:15:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'I'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:15:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 17:15:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 17:15:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	14 Oct 2020 18:24:15
DataPoint Verified.	Coder Import (b) (4)	01 Oct 2020 17:18:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue swelling and oedema, PT: Lip swelling, LLT: Swollen lips - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 17:18:56
Data point term sent to Coder	System	01 Oct 2020 17:17:40
User entered 'Swollen Lips'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	14 Oct 2020 18:24:15
DataPoint Verified.		
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '5 Sep 2020'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 17:17:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '8 Sep 2020'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 17:17:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'No (N)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

US3902030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Related (RELATED)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Not Related (NOT RELATED)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
DataPoint Un-verified.	Taylor Atkinson (b) (4)	24 Nov 2020 17:51:44
User entered 'None (NONE)' reason for change:	Taylor Atkinson (b) (4)	24 Nov 2020 17:51:44
Data Entry Error	(b) (4)	
User closed query 'Per CDM: Previous query response indicates, "Per PI, the AE ultimately determining IP withdrawal is Hives," however, Action taken with investigational product is 'Investigational Product Withdrawn'. Only the AE that led to the drug being withdrawn should have this recorded. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:10:57
Query 'Per CDM: Previous query response indicates, "Per PI, the AE ultimately determining IP withdrawal is Hives," however, Action taken with investigational product is 'Investigational Product Withdrawn'. Only the AE that led to the drug being withdrawn should have this recorded. Please clarify and update as appropriate.' answered with 'All 3 AEs started at the same time and were related, so they all led to PI decision' (Site from DM).	Taylor Atkinson (b) (4)	23 Oct 2020 18:57:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User opened query 'Per CDM: Previous query response indicates, "Per PI, the AE ultimately determining IP withdrawal is Hives," however, Action taken with investigational product is 'Investigational Product Withdrawn'. Only the AE that led to the drug being withdrawn should have this recorded. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:02:29
User closed query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:02:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate. ' answered with 'Per PI, the AE ultimately determining IP withdrawal is Hives.' (Site from DM).	Bram Swarr (b) (4)	12 Oct 2020 18:10:06
User opened query 'Per CDM: All 3 AEs have Action taken with investigational product recorded as 'Investigation Product Withdrawn'. Please clarify which AE actually led to the study drug being withdrawn, as there should only be one, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:10:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Taylor Atkinson (b) (4) (b) (4)	01 Oct 2020 17:17:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

None

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	29 Oct 2020 16:40:49
DataPoint Verified.	System	28 Oct 2020 18:12:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Bram Swarr (b) (4)	28 Oct 2020 18:12:51
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:12:51
User entered '1' reason for change: Data Entry Error	System	28 Oct 2020 18:12:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 18:24:15
DataPoint Verified.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
User entered '0'	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
	(b) (4), (b) (6)	29 Oct 2020 16:40:52
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 10:10:59
User closed query 'Per CDM: Other action taken is checked as 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of SWOLLEN LIPS. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:12:48
Query 'Per CDM: Other action taken is checked as 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of SWOLLEN LIPS. Please clarify and update as appropriate.' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	28 Oct 2020 18:12:35
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:12:35
User entered '0' reason for change: Data Entry Error	Bram Swarr (b) (4)	14 Oct 2020 18:24:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:23:48
User opened query 'Per CDM: Other action taken is checked as 'Concomitant Medication', however, there are no corresponding medications recorded on the Prior and Concomitant Medications form with an Indication of SWOLLEN LIPS. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 17:17:11
User entered '1'	Taylor Atkinson (b) (4)	(b) (4)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered '0'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:15
User entered empty.	Taylor Atkinson (b) (4)	01 Oct 2020 17:17:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 17:17:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 17:17:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) [REDACTED] Murray Kimmel (b) (4) [REDACTED] [REDACTED]	12 Apr 2021 08:23:27 09 Apr 2021 16:41:57
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'By the time site was alerted of the upper respiratory infection, all symptoms had already resolved. Subject did not report symptoms in their diary and they only volunteered this information during prompting on their safety call. Subject was assessed by an urgent care and deemed to have the URI. Subject re-educated on alerting the site through their ed diary.' (Site from DM). User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM). DataPoint Verified.	Taylor Atkinson (b) (4) (b) (4) (b) (4), (b) (6) [REDACTED] (b) (4), (b) (6) [REDACTED]	 29 Mar 2021 09:35:35 17 Mar 2021 16:33:50
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0. User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder User entered 'Upper Respiratory Infection'	Coder Import (b) (4) (b) (4) Coder Import (b) (4) (b) (4) System Bram Swarr (b) (4) [REDACTED]	08 Mar 2021 16:09:39 08 Mar 2021 16:09:39 08 Mar 2021 16:08:53 08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'Yes (Y)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

US3902030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'No (N)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'No (N)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '13 Jan 2021'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'No (N)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '20 Jan 2021'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'No (N)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

US3902030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'Not Applicable (NOT APPLICABLE)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'I'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	09 Apr 2021 16:41:57
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:33:50
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 16:08:46

US3902030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 16:08:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:15:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:15:27
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 17:28:45
User entered 'arthralgia'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '11 Sep 2020'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:19:22
User entered '14 Sep 2020'	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Related (RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'None (NONE)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'I'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:28:24

US3902030

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:28:24

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:24:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:24:40
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 17:30:48
User entered 'myalgia'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:19:22
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '11 Sep 2020'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '11 Sep 2020'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Related (RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'None (NONE)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

None

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Apr 2021 17:30:21
User entered '1' reason for change: Data Entry Error	Bram Swarr (b) (4)	28 Apr 2021 17:30:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Apr 2021 17:29:56
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:29:56

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:32:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:32:06
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 17:31:48
User entered 'fatigue'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:19:22
User entered 'Yes (Y)'	Bram Swarr (b) (4) [REDACTED]	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '11 Sep 2020'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '14 Sep 2020'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Related (RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'None (NONE)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'I'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:31:10

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:39:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 18:39:38
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 17:32:49
User entered 'injection site redness'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '11 Sep 2020'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '14 Sep 2020'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'No (N)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Related (RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Not Related (NOT RELATED)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'None (NONE)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'I'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered '0'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	29 Apr 2021 18:13:07
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:19:22
User entered empty.	Bram Swarr (b) (4)	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:32:01

US3902030

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:44:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:32:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:44:45

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:33:59
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject took acetaminophen for solicited AE symptoms recorded in medhx' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:01:24
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject took acetaminophen for solicited AE symptoms recorded in medhx' (Site from DM).	Bram Swarr (b) (4)	05 Mar 2021 21:49:12
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 11:55:45
	(b) (4), (b) (6)	16 Sep 2020 16:29:40
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:37:30
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING, PRODUCT: INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE, PRODUCTSYNONYM: NOVOLIN 70/30 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 06:27:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 06:27:54
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
Data point term sent to Coder	System	16 Sep 2020 15:39:25
User entered 'Novolin 70/30'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Diabetes Type II'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '25'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:29:53
DataPoint Un-verified.	Katrina Carlson (b) (4)	26 Sep 2020 16:05:22
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	26 Sep 2020 16:05:22
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Other (OTHER)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:29:53
User closed query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:39:30
Query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 16:05:29
DataPoint Un-verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	Katrina Carlson (b) (4)	26 Sep 2020 16:05:22
User opened query 'Per CDM: Please review "Other Unit" as there is an available option for "IU" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:26:35
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'units'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'twice daily (BID)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Subcutaneous (SUBCUTANEOUS)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un UNK 2019'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:03:57
User entered 'No (N)' reason for change: Data Entry Error	Bram Swarr (b) (4)	28 Oct 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:03:57
User entered '20 Oct 2020' reason for change: New Information	Bram Swarr (b) (4)	28 Oct 2020 18:03:57
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:38:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 15:38:50
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:50
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:38:38
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User entered '2'	System	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User entered '1'	System	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:34
User entered '804 (804)'	System	16 Sep 2020 15:38:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
	(b) (4), (b) (6)	16 Sep 2020 16:40:11
DataPoint Verified.	Coder Import (b) (4)	16 Sep 2020 15:41:39
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 HYDROCHLORIDE, PRODUCTSYNONYM: METFORMIN HCL - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:41:39
Data point term sent to Coder User entered 'Metformin HCL'	System	16 Sep 2020 15:40:26
	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Diabetes Type II'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '1000'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un UNK 2014'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:39:44
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:39:44

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:39:44

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:39:44

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
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)	16 Sep 2020 15:41:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:41:39
Data point term sent to Coder	System	16 Sep 2020 15:40:27
User entered 'Amlodipine'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Hypertension'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '5'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un UNK 2014'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:06:53
User entered 'No (N)' reason for change: New Information	Bram Swarr (b) (4)	28 Oct 2020 18:06:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:06:53
User entered 'un Sep 2020' reason for change: Data Entry Error	Bram Swarr (b) (4)	28 Oct 2020 18:06:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User entered '1'	System	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User entered '1'	System	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:02:02
User entered '804 (804)'	System	16 Sep 2020 15:40:19

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
	(b) (4), (b) (6)	16 Sep 2020 16:40:11
DataPoint Verified.	Coder Import (b) (4)	16 Sep 2020 15:48:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:48:45
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 15:47:41
User entered 'Omeprazole'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'GERD'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '20'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'twice daily (BID)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un Mar 2020'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:47:34
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Sep 2020 15:47:34

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:47:34

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:47:34

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:50:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:50:39
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 15:49:48
User entered 'Lyrica'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
Query ""	(b) (4), (b) (6)	24 Nov 2020 07:43:27
Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. "		
' canceled (Site from DM).		
User opened query ""	(b) (4), (b) (6)	07 Nov 2020 15:01:08
Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. "		
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Peripheral Neuropathy'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '300'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un Mar 2020'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:49:33
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:49:33

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:49:33

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:49:33

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
	(b) (4), (b) (6)	
DataPoint Verified.	Coder Import (b) (4)	16 Sep 2020 16:40:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4)	16 Sep 2020 15:51:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:51:35
Data point term sent to Coder User entered 'Lovastatin'	System Taylor Atkinson (b) (4)	16 Sep 2020 15:50:49 16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Hypercholestrolemia'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '20'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un UNK 2018'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:10
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:50:10

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:50:10

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:50:10

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:52:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:52:38
Data point term sent to Coder	System	16 Sep 2020 15:51:50
User entered 'Lisinopril'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Hypertension'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '40'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un UNK 2015'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:07:17
User entered 'No (N)' reason for change: New Information	Bram Swarr (b) (4)	28 Oct 2020 18:07:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
DataPoint Un-verified.	Bram Swarr (b) (4)	28 Oct 2020 18:07:17
User entered '20 Oct 2020' reason for change: New Information	Bram Swarr (b) (4)	28 Oct 2020 18:07:17
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User entered '1'	System	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User entered '1'	System	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:39
User entered '804 (804)'	System	16 Sep 2020 15:50:50

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:52:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:52:38
Data point term sent to Coder	System	16 Sep 2020 15:51:50
User entered 'Hydrochlorothiazide'	Taylor Atkinson (b) (4) (b) (4)	16 Sep 2020 15:51:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Hypertension'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '25'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un UNK 2015'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:51:31
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:51:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:51:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:51:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
	(b) (4), (b) (6)	16 Sep 2020 16:40:11
DataPoint Verified.	Coder Import (b) (4)	16 Sep 2020 15:55:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 15:55:37
Data point term sent to Coder	System	16 Sep 2020 15:54:53
Data point term sent to Coder	System	16 Sep 2020 15:53:52
User entered 'Jardiance'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:53:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 15:53:58
User entered 'Diabetes Type II' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 15:53:03
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '25'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'once daily (QD)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'un UNK 2016'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:03
	(b) (4)	

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:53:03

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:53:03

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 15:53:03

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 15:54:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 15:54:38
Data point term sent to Coder	System	16 Sep 2020 15:53:52
User entered 'Benadryl'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'No (N)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Hives'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '25'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'as needed (PRN)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '09 Sep 2020'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered '0'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:29:53
User closed query 'Per CDM: Ongoing?' is recorded as 'Yes', however, the corresponding AE has an End Date recorded as 21SEP2020. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:26:30
Query 'Per CDM: Ongoing?' is recorded as 'Yes', however, the corresponding AE has an End Date recorded as 21SEP2020. Please clarify and update as appropriate.' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	12 Oct 2020 18:13:18
DataPoint Un-verified.	Bram Swarr (b) (4)	12 Oct 2020 18:13:08
User entered 'No (N)' reason for change: Data Entry Error	Bram Swarr (b) (4)	12 Oct 2020 18:13:08
User opened query 'Per CDM: Ongoing?' is recorded as 'Yes', however, the corresponding AE has an End Date recorded as 21SEP2020. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 14:38:43
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:29:53
DataPoint Un-verified.	Bram Swarr (b) (4)	12 Oct 2020 18:13:08
User entered '18 Sep 2020' reason for change: Data Entry Error	Bram Swarr (b) (4)	12 Oct 2020 18:13:08
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered empty.	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User closed query 'Per DM CLR: Please review if this refers to recorded AE of HIVES. If so, please note that AE of HIVES is recorded as "Was this a Solicited Adverse Reaction?" as NO. Please review entries and reconcile AE and CM entries. Update as appropriate or provide clarification ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 18:10:52
Query 'Per DM CLR: Please review if this refers to recorded AE of HIVES. If so, please note that AE of HIVES is recorded as "Was this a Solicited Adverse Reaction?" as NO. Please review entries and reconcile AE and CM entries. Update as appropriate or provide clarification ' answered with 'Updated entry error' (Site from DM).	Taylor Atkinson (b) (4)	21 Dec 2020 23:21:11
DataPoint Un-verified.	Taylor Atkinson (b) (4)	21 Dec 2020 23:21:03
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	21 Dec 2020 23:21:03
User opened query 'Per DM CLR: Please review if this refers to recorded AE of HIVES. If so, please note that AE of HIVES is recorded as "Was this a Solicited Adverse Reaction?" as NO. Please review entries and reconcile AE and CM entries. Update as appropriate or provide clarification ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 07:00:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:11
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User entered empty.	System	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User entered empty.	System	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:45
User entered empty.	System	16 Sep 2020 15:53:45

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:47:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:47:20
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
Data point term sent to Coder User entered 'lisinopril'	System Bram Swarr (b) (4)	28 Oct 2020 18:08:28 28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'hypertension'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '20'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'mg (mg)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'once daily (QD)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '20 Oct 2020'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '0'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 18:08:01

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User coded data point as ATC: ALIMINARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE, PRODUCTSYNONYM: NOVOLIN 70/30 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:07:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:07:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
Data point term sent to Coder	System	28 Oct 2020 18:09:29
User entered 'novolin 70/30'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'diabetes II'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '25'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'IU (IU)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'once daily (QD)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '20 Oct 2020'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '0'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 18:08:39

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE, PRODUCTSYNONYM: NOVOLIN 70/30 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:07:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:07:51
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
Data point term sent to Coder	System	28 Oct 2020 18:10:31
User entered 'novolin 70/30'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'diabetes II'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '20'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'IU (IU)'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'other (OTHER)'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'nightly'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '20 Oct 2020'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '0'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Yes (Y)'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Bram Swarr (b) (4)	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 18:09:41

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:25:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:25:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
Data point term sent to Coder	System	29 Oct 2020 11:36:25
User entered 'Acetaminophen'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:24:05
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' answered with 'please see Diary Dose 1 crf which shows pain occurring on the dates indicated' (Site from DM).	Bram Swarr (b) (4)	14 Jan 2021 14:40:23
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of INJECTION SITE PAIN in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:45:58
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Injection Site Pain'	Taylor Atkinson (b) (4) (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '1000'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'as needed (PRN)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '06 Sep 2020'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '0'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'No (N)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered '08 Sep 2020'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:03
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User entered empty.	System	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User entered empty.	System	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:50
User entered empty.	System	29 Oct 2020 11:35:31

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 23:23:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 23:23:48
Data point term sent to Coder	System	08 Mar 2021 16:10:56
User entered 'amoxicillin'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered 'No (N)'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered 'AE #4: Upper Respiratory Infection'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered '500'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered 'mg (mg)'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered 'once daily (QD)'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered empty.	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered '13 Jan 2021'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered '0'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered 'No (N)'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered '20 Jan 2021'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:16
User entered 'No (N)'	Bram Swarr (b) (4)	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User entered '1'	System	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User entered '1'	System	08 Mar 2021 16:10:13

US3902030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:44:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:54
User entered '804 (804)'	System	08 Mar 2021 16:10:13

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:44:45

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:53:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:29
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	24 Nov 2020 23:09:25

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:44:45

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:44
	(b) (4), (b) (6)	09 Apr 2021 20:04:23
User closed query 'please obtain medical records to capture any medications given during procedure and/or any AEs. Medication administration record and Anesthesia Record. ' (Site from CRA).	Taylor Atkinson (b) (4)	09 Apr 2021 18:58:12
Query 'please obtain medical records to capture any medications given during procedure and/or any AEs. Medication administration record and Anesthesia Record. ' answered with 'Site has sent subject a medical records request form' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 16:35:51
User opened query 'please obtain medical records to capture any medications given during procedure and/or any AEs. Medication administration record and Anesthesia Record. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 16:34:39
DataPoint Verified.	Taylor Atkinson (b) (4)	08 Dec 2020 20:36:23
User entered '24 Nov 2020'	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:44:45

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:39
User entered 'Hiatal Hernia Repair'	Taylor Atkinson (b) (4)	08 Dec 2020 20:36:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:44:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:39
User entered 'Medical History (MH)'	Taylor Atkinson (b) (4)	08 Dec 2020 20:36:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:44:45

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	16 Apr 2021 20:42:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:34:39
User entered empty.	Taylor Atkinson (b) (4)	08 Dec 2020 20:36:23
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:44:45

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:54:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:22
User entered '1 Oct 2020'	Bram Swarr (b) (4)	28 Oct 2020 18:01:32

US3902030

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:44:45

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:54:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:22
User entered 'AE (specify) (ADVERSE EVENT)'	Bram Swarr (b) (4)	28 Oct 2020 18:01:32

US3902030

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:44:45

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 05:54:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:11:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 16:36:01
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:42:50
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'updated' (Site from DM).	Bram Swarr (b) (4)	05 Mar 2021 21:44:52
User entered 'AE #1' reason for change: Data Entry Error	Bram Swarr (b) (4)	05 Mar 2021 21:44:47
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:24:45
User closed query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:41:09
Query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	Taylor Atkinson (b) (4)	16 Dec 2020 14:04:34
DataPoint Un-verified.	Taylor Atkinson (b) (4)	16 Dec 2020 14:04:28
User entered '#1' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	16 Dec 2020 14:04:28

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:44:45

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 06:54:07
	(b) (4), (b) (6)	02 Dec 2020 17:11:46
User closed query 'per AE CRF Hives = AE #1. Please update' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 17:11:42
User closed query 'Per CDM re-query: Previous query response states 'updated', however the response for 'If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify' is reported as 'HIVES' please review and confirm if the response can be updated as AE#1, else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 03:52:26
Query 'Per CDM re-query: Previous query response states 'updated', however the response for 'If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify' is reported as 'HIVES' please review and confirm if the response can be updated as AE#1, else clarify. ' answered with 'updated per query' (Site from DM).	Bram Swarr (b) (4)	25 Nov 2020 19:07:12
Query 'per AE CRF Hives = AE #1. Please update' answered with 'updated per query' (Site from CRA).	Bram Swarr (b) (4)	25 Nov 2020 19:07:07
User entered 'HIVES (AE #1)' reason for change: Data Entry Error	Bram Swarr (b) (4)	25 Nov 2020 19:07:02
User closed query 'Per CDM: per response to query on ASE form, Hives is what lead to IP discontinuation. Please record that AE record number here instead of details.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 02:00:08
User opened query 'Per CDM re-query: Previous query response states 'updated', however the response for 'If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify' is reported as 'HIVES' please review and confirm if the response can be updated as AE#1, else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 02:00:05

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:44:45

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'per AE CRF Hives = AE #1. Please update' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:19:20
Query 'Per CDM: per response to query on ASE form, Hives is what lead to IP discontinuation. Please record that AE record number here instead of details.' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	24 Nov 2020 17:48:20
DataPoint Un-verified.	(b) (4)	
	Taylor Atkinson (b) (4)	24 Nov 2020 17:48:15
User entered 'HIVES' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 17:48:15
User opened query 'Per CDM: per response to query on ASE form, Hives is what lead to IP discontinuation. Please record that AE record number here instead of details.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:59:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:22
User entered 'hives, swollen lips, sore hands'	Bram Swarr (b) (4)	28 Oct 2020 18:01:32