

US3892034 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:21:56

All time stamps listed in this document are displayed in GMT

US3892034

Form: Participant Creation

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

[Participant ID](#)

US3892034

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

US3892034

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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) 09 Mar 2021 17:50:54

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Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	CATARACTS BILATERAL
Start date (dd MMM yyyy)	UN DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	ODONTOGENIC DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	RIGHT CORNEAL TRANSPLANT
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	RIGHT KERATOCONUS
Start date (dd MMM yyyy)	(b) (6) 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	LEFT CORNEAL TRANSPLANT
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	PRED FORTE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (10)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

US3892034

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Condition	LEFT KERATOCONUS
Start date (dd MMM yyyy)	(b) (6) 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 17:50:54

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Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:08 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:08
Height (<i>xxx.x</i>)	165.5 cm
Weight (<i>xxx.x</i>)	80.4 kg
BMI (<i>xxx.x</i>)	29.35351 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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) 09 Mar 2021 17:50:54

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 17:50:54

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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 False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 17:50:54

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	LIVES WITH FAMILY MEMBERS WHO TRAVEL, RUNS (b) (6)

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 110345

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) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

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) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:08
Temperature (xxx.x)	96.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:14
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

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) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 13:38 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 13:38

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) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

13:12 (24 HR)

Collection date and time (derived)

31 AUG 2020 13:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:05	31 AUG 2020 13:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 14:17

PC Open Date & Time

31 AUG 2020 13:58

PC Close Date & Time

31 AUG 2020 16:28

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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	31 AUG 2020 23:57
PC Open Date & Time	31 AUG 2020 17:23
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 13:09

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 13:27

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:04

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

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

97.1 °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 17:09

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

31 AUG 2020 14:19

PC Open Date & Time

31 AUG 2020 13:58

PC Close Date & Time

31 AUG 2020 16:28

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

31 AUG 2020 23:59

PC Open Date & Time

31 AUG 2020 17:23

PC Close Date & Time

01 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

01 SEP 2020 13:10

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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

02 SEP 2020 13:28

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 15:40

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 17:10

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 22:48

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 14:21
PC Open Date & Time	31 AUG 2020 13:58
PC Close Date & Time	31 AUG 2020 16:28

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 00:00

PC Open Date & Time	31 AUG 2020 17:23

PC Close Date & Time	01 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	01 SEP 2020 13:11
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

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 ☒

PRODUCTION RELEASE (v12.003

54 of 2276

EAB) (1725)

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	02 SEP 2020 13:29
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	03 SEP 2020 15:41
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	04 SEP 2020 16:05
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	05 SEP 2020 17:20
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	06 SEP 2020 22:49
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3892034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☒
	Clinic ☐
Folder OID	VISIT2

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:08
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:46
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3892034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 12:07 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 12:07

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

US3892034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

11:20 (24 HR)

Collection date and time (derived)

28 SEP 2020 11:20

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:27	28 SEP 2020 11:27
Nasopharyngeal Swab 2	No		

US3892034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 12:42

PC Open Date & Time

28 SEP 2020 12:27

PC Close Date & Time

28 SEP 2020 14:57

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	29 SEP 2020 10:46
PC Open Date & Time	28 SEP 2020 15:52
PC Close Date & Time	29 SEP 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 09:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 09:40

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 11:30

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 10:04

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 11:13

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

28 SEP 2020 12:43

PC Open Date & Time

28 SEP 2020 12:27

PC Close Date & Time

28 SEP 2020 14:57

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

29 SEP 2020 10:47

PC Open Date & Time

28 SEP 2020 15:52

PC Close Date & Time

29 SEP 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

30 SEP 2020 09:33

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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

01 OCT 2020 09:40

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 11:30

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 10:05

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 11:14

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 12:44
PC Open Date & Time	28 SEP 2020 12:27
PC Close Date & Time	28 SEP 2020 14:57

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:48
PC Open Date & Time	28 SEP 2020 15:52
PC Close Date & Time	29 SEP 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	30 SEP 2020 09:34
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	01 OCT 2020 09:41
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	02 OCT 2020 11:31
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	04 OCT 2020 10:22
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

Yes ☐	
PC Time stamp	05 OCT 2020 11:14
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3892034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 10:59
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3892034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	11:12 (24 HR)
Collection date and time (derived)	26 OCT 2020 11:12

US3892034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:55

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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	31 OCT 2020 17:34:17
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

11 NOV 2020 18:45:46

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 16:23:11
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 22:00:55

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 13:31:06
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 14:04:54
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

09 DEC 2020 09:12:52

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 10:38:21
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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	23 DEC 2020 14:55:48
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 23:55:24
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 11:30:33
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	14 JAN 2021 22:11:01
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	20 JAN 2021 09:57:14
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 13:33:49

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 10:14:22

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 15:40:24

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 14:50:56

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 01:53:05

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 07:04:31

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 09:00:17

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 07:52:06

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 11:53:39

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 11:52:06

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 09:06:09

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 01:33:19

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 404

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

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

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

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

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

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JAN 2022 00:01

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09 JAN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 FEB 2022 00:01

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13 FEB 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAR 2022 00:01

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27 MAR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAR 2022 00:01

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03 APR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 APR 2022 00:01

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10 APR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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17 APR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 APR 2022 00:01

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24 APR 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 APR 2022 00:01

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01 MAY 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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05 JUN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2022 00:01

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12 JUN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 JUN 2022 00:01

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19 JUN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2022 00:01

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26 JUN 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 JUN 2022 00:01

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03 JUL 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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10 JUL 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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17 JUL 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 691

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

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

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

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

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

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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20 JUL 2022 00:01

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24 JUL 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 698

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

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

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

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

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

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 JUL 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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07 AUG 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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10 AUG 2022 00:01

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14 AUG 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 AUG 2022 00:01

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21 AUG 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 AUG 2022 00:01

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28 AUG 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 AUG 2022 00:01

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04 SEP 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 768

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

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

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

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

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

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

DAY 796

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

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

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

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

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

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

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 ☐

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3892034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:21:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 01:52:28

US3892034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:50:54

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3892034

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

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) _____

US3892034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3892034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	11:14 (24 HR)
Collection date and time (derived)	15 MAR 2021 11:14

US3892034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 May 2021 21:11:21

Generated On: 10 Jun 2021 10:21:56

Date of Contact	23 APR 2021
Time of Contact	12:30
Date and Time of Contact (derived)	23 APR 2021 12:30
Type of Contact	Clinic Visit - Scheduled☐ Clinical Visit - Unscheduled☐ Safety Call☒ Convalescent Tele-visit☐
Has the subject reported symptoms of SARS-COV-2?	Yes☒ No☐

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:21:56

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:21:56

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	
Assessment Not Done	
O2 Saturation	
O2 Saturation Units	
Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Fatigue	None	☐

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:21:56

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:21:56

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 May 2021 21:11:20

Generated On: 10 Jun 2021 10:21:56

Date of Visit 23 APR 2021

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

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

Date of Test 23 APR 2021

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

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:21:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3892034

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 10 Jun 2021 10:21:56

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3892034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	23 APR 2021

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

Folder OID	SICKD1

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 APR 2021
Time of assessment (00:00-23:59)	19:07 (24 HR)
Vital Signs Date and Time (derived)	23 APR 2021 19:07
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 APR 2021

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

US3892034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 APR 2021

US3892034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3892034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Were vital signs assessed?	Yes ☐
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3892034

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

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.

US3892034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:21:56

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3892034

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

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	21 JAN 2021

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

Folder OID	UNBLND_DECIDE

US3892034

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

Date of updated informed consent (dd MMM yyyy) 21 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3892034

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00-23:59)	11:17 (24 HR)
Collection date and time (derived)	21 JAN 2021 11:17

US3892034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	21 JAN 2021

Collection time (00:00 - 23:59)	11:29

Collection Date and Time (derived)	21 JAN 2021 11:29

US3892034

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 16:21:40

Generated On: 10 Jun 2021 10:21:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3892034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

RIGHT LOWER QUADRANT
PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3892034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT ATTRIBUTED TO ABDOMINAL EXERCISES. RESOLVED WITHOUT TREATMENT
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 (2)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID	USA-US209-2021-MRNA-1273-P30 1000001
Adverse event	TRAUMATIC BRAIN INJURY
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	07 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	08 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	08 JAN 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

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

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

SUBJECT FELL ON ICE AND
LANDED ON HIS FACE. HE
LOST CONSCIOUSNESS FOR 13
MINUTES AND WAS
TRANSPORTED TO THE
HOSPITAL. HE ALSO
FRACTURED BOTH ORBITS
AND ZYGOMATIC ARCHES AND
NASAL BONE. HE REPORTS
THAT THE CT BRAIN
REVEALED SMALL
HEMORRHAGE THAT
RESOLVED BY THE NEXT DAY
AND HE WAS DISCHARGED
AFTER ONE OVERNIGHT.

INFECTION DISEASE:
SARS-COV-2 BY PCR NEGATIVE.
COLLECTED ON 07 JAN. 2021 AT
13:13 MST.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3892034

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

FOREIGN BODY RIGHT 3RD
FINGER

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	FOREIGN BODY REMOVED AND SUBJECT REPORTS RESOLUTION.
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 (4)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

FRACTURE ORBITS BILATERAL
NON-DISPLACED

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	FRACTURE DID NOT PROLONG HOSPITALIZATION FOR TRAUMATIC BRAIN INJURY. DID NOT REQUIRE SURGERY.
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) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

FRACTURE ZYGOMATIC
ARCHES BILATERAL
NON-DISPLACED

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	FRACTURE DID NOT PROLONG HOSPITALIZATION FOR TRAUMATIC BRAIN INJURY. NO SURGERY REQUIRED.
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 (6)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

MINIMAL SUBARACHNOID
HEMORRHAGE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS HOSPITALIZED FOR TBI, THE HEMORRHAGE DID NOT PROLONG HOSPITALIZATION.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

FRONTAL SUBDURAL
HEMATOMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	THE HEMATOMA DID NOT PROLONG HOSPITALIZATION AND RESOLVED ON IMAGING THE NEXT DAY.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

FRACTURE LEFT AND RIGHT
MAXILLARY SINUS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	FRACTURE DID NOT PROLONG HOSPITALIZATION FOR TBI.
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)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID

Adverse event

FALL FROM ON ICE GROUND

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3892034

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

AEID	
Adverse event	
Was this a medically-attended AE?	Yes ☐ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☐
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☐
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 23:03:47

Generated On: 10 Jun 2021 10:21:56

Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	
Other medically important event	
Relationship to investigational product	Not Related ☐
	Related ☐
	Not Applicable ☐
Relationship to Study Procedure	Not Related ☐
	Related ☐
	Not Applicable ☐
Action taken with investigational product	None ☐
	Dose Delayed ☐
	Investigational Product ☐
	Withdrawn ☐
	Not Applicable ☐
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal ☐
	Not Recovered/Not Resolved ☐
	Recovered/Resolved ☐
	Recovered/Resolved with ☐
	Sequelae ☐
	Recovering/Resolving ☐
	Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

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

Yes ☒

No ☐

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

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Name of Medication METAMUCIL

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify TSP

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 (1)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN AUG 2019
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication FOREIGN BODY RIGHT 3RD
FINGER

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify CC

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	INTRADERMAL	
Start date (dd MMM yyyy)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	11 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication FRACTURE ORBIT BILATERAL

Dose per administration 875

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication FRACTURE ORBIT BILATERAL

Dose per administration 200

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 (5)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

Name of Medication ROBITUSSIN DM

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:39:59

Generated On: 10 Jun 2021 10:21:56

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 APR 2021
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 16:25:49

Generated On: 10 Jun 2021 10:21:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 JAN 2021	CT BRAIN/ HEAD	Diagnostic	
11 JAN 2021	REMOVAL FOREIGN BODY RIGHT 3RD FINGER	Adverse Event	
07 JAN 2021	CT MAXILLOFACIAL	Adverse Event	
07 JAN 2021	CHEST X-RAY	Diagnostic	
07 JAN 2021	PELVIS X-RAY	Diagnostic	
08 JAN 2021	CT BRAIN/HEAD	Adverse Event	
07 JAN 2021	CT SCAN SPINE/CERVICAL	Adverse Event	
25 FEB 2021	CT BRAIN/HEAD	Diagnostic	

US3892034

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:21:56

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:21:56

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 ☐

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

SAEID	USA-US209-2021-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

SAEID	USA-US209-2021-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/JAN/2021 14:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

SAEID	USA-US209-2021-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/FEB/2021 11:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

SAEID	USA-US209-2021-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 13:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 16:25:57

Generated On: 10 Jun 2021 10:21:56

SAEID	USA-US209-2021-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/FEB/2021 10:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3892034 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

US3892034

Form: Participant Creation

Generated On: 10 Jun 2021 10:21:56

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'US3892034'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:39:42

US3892034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:01

US3892034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:39:44

US3892034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:01

US3892034

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'SCRN'	System	31 Aug 2020 19:44:01

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:39:45

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '59'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'YEARS'	System	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '59'	System	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Male (M)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '1'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:21:56

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:23

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Aug 2020'	System	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '2020'	System	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Amendment 3 (3)'	Andryelle Toledo (b) (4)	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:53

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:39:44

US3892034

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:21:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1'	System	31 Aug 2020 19:44:57

US3892034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:44:57

US3892034

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:21:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:44:05

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 19:45:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 19:45:52
Data point term sent to Coder	System	02 Sep 2020 19:45:15
User entered 'CATARACTS BILATERAL'	Andryelle Toledo (b) (4)	02 Sep 2020 19:44:33
	(b) (4)	

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'UN Dec 2018'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Dec 2018'	System	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '2018'	System	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	02 Sep 2020 19:44:33

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 19:50:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 19:50:00
Data point term sent to Coder	System	02 Sep 2020 19:49:25
Coding entries removed.	Andryelle Toledo (b) (4)	02 Sep 2020 19:49:03
User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Sep 2020 19:49:03
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 19:45:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 19:45:53
Data point term sent to Coder	System	02 Sep 2020 19:45:15
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Andryelle Toledo (b) (4)	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'UN UNK 2019'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 2019'	System	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '2019'	System	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	02 Sep 2020 19:45:10

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:47:44
Data point term sent to Coder	System	02 Sep 2020 19:46:20
User entered 'SEASONAL ALLERGIES'	Andryelle Toledo (b) (4)	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'UN UNK 2019'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 2019'	System	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '2019'	System	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	02 Sep 2020 19:45:28

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth disorder, LLT: Tooth disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 10:43:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 10:43:48
User signature succeeded.	Michael Adams (b) (4) (b) (4)	09 Mar 2021 17:50:55
Data point term sent to Coder	System	22 Jan 2021 01:09:32
User entered 'odontogenic disease'	Andryelle Toledo (b) (4) (b) (4)	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 2019'	(b) (4) Andryelle Toledo (b) (4)	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 2019'	System	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '2019'	System	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	22 Jan 2021 01:09:19

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal transplant, LLT: Corneal transplant - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Feb 2021 22:21:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 22:21:01
Data point term sent to Coder	System	25 Feb 2021 22:20:00
User entered 'Right Corneal transplant'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 1977'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 1977'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 1977'	System	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1977'	System	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 1977'	System	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1977'	System	25 Feb 2021 22:19:36

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Corneal structural change, deposit and degeneration, PT: Keratoconus, LLT: Keratoconus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 07:15:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:15:10
Data point term sent to Coder	System	25 Feb 2021 22:21:02
User entered 'Right Keratoconus'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	25 Feb 2021 22:26:11
User entered (b) (6) 1960' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:26:11
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	25 Feb 2021 22:20:29
User entered 'un UNK 1960'	System	25 Feb 2021 22:20:29
	Andryelle Toledo (b) (4)	25 Feb 2021 22:20:29
	(b) (4)	

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 1977'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered (b) (6) 1960'	System	25 Feb 2021 22:26:11
User entered 'Jan 1960'	System	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1960'	System	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 1977'	System	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1977'	System	25 Feb 2021 22:20:29

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal transplant, LLT: Corneal transplant - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:38:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:38:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal transplant, LLT: Corneal transplant - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:23:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:23:02
Data point term sent to Coder	System	25 Feb 2021 22:22:03
User entered 'Left corneal transplant'	Andryelle Toledo (b) (4)	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 1981'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 1981'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 1981'	System	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1981'	System	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 1981'	System	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1981'	System	25 Feb 2021 22:21:28

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 09:12:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 09:12:48
User signature succeeded.	Michael Adams (b) (4) (b) (4)	09 Mar 2021 17:50:55
Data point term sent to Coder	System	25 Feb 2021 22:23:04
User entered 'Pred Forte allergy'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 1981'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 1981'	System	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1981'	System	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	25 Feb 2021 22:22:16

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:24:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:24:02
Data point term sent to Coder	System	25 Feb 2021 22:23:04
User entered 'Depression'	Andryelle Toledo (b) (4)	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 2018'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 2018'	System	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '2018'	System	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	25 Feb 2021 22:22:40

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:24:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 22:24:01
Data point term sent to Coder	System	25 Feb 2021 22:23:04
User entered 'Anxiety'	Andryelle Toledo (b) (4)	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 2018'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 2018'	System	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '2018'	System	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	25 Feb 2021 22:22:55

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Corneal structural change, deposit and degeneration, PT: Keratoconus, LLT: Keratoconus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 10:43:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:43:11
Data point term sent to Coder	System	25 Feb 2021 22:24:05
User entered 'Left Keratoconus'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	25 Feb 2021 22:25:57
User entered (b) (6) 1960' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:25:57
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	25 Feb 2021 22:23:23
User entered 'un UNK 1960'	System	25 Feb 2021 22:23:23
	Andryelle Toledo (b) (4)	25 Feb 2021 22:23:23
	(b) (4)	

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'un UNK 1981'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered (b) (6) 1960'	System	25 Feb 2021 22:25:57
User entered 'Jan 1960'	System	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1960'	System	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'Jan 1981'	System	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1981'	System	25 Feb 2021 22:23:23

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '12:08'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '31 Aug 2020 12:08'	System	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '165.5' cm	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58
DataPoint set to visible.	(b) (4) System	31 Aug 2020 19:44:57

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '80.4' kg	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58
DataPoint set to visible.	(b) (4) System	31 Aug 2020 19:44:57

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '29.35351'	System	02 Sep 2020 19:49:58
DataPoint set to visible.	System	31 Aug 2020 19:44:57

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'kg/m2'	System	02 Sep 2020 19:49:58
DataPoint set to visible.	System	31 Aug 2020 19:44:57

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'bpm'	System	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'breaths/min'	System	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'mmHg'	System	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'mmHg'	System	02 Sep 2020 19:49:58

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55

US3892034

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55

US3892034

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:50:24

US3892034

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:50:24

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

[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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

[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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

[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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '1'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '1'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15

US3892034

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:21:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'lives with family members who travel,	(b) (4)	
runs (b) (6) '	Andryelle Toledo (b) (4)	31 Aug 2020 19:46:15
	(b) (4)	

US3892034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:27

US3892034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:27

US3892034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	31 Aug 2020 19:46:27

US3892034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'VISIT1'	System	31 Aug 2020 19:46:27

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:04:37

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '110345'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:04:37

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 19:04:37

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

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)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:51

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

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)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	Andryelle Toledo (b) (4)	31 Aug 2020 19:46:51

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:51

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:51

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:46:51

US3892034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:21:56

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:17:03
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:46:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:46:27

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44
	(b) (4)	

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '12:08'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '31 Aug 2020 12:08'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 05:51:52
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI: NCS' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	18 Sep 2020 18:20:29
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:23:10
User entered '96.7' F	Andryelle Toledo (b) (4) (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '55'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '14'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. 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). Query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. 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 'Per PA: NCS' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:28:53
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. 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).	Andryelle Toledo (b) (4)	23 Mar 2021 13:47:41
User signature succeeded.	(b) (4)	
User entered '144'	Michael Adams (b) (4)	09 Mar 2021 17:50:55
	(b) (4)	
	Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44
	(b) (4)	

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. 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). Query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. 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 'Per PA: NCS' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:28:55
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. 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).	Andryelle Toledo (b) (4)	23 Mar 2021 13:47:55
User signature succeeded.	(b) (4)	
User entered '92'	Michael Adams (b) (4)	09 Mar 2021 17:50:55
	(b) (4)	
	Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44
	(b) (4)	

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:21:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '14:14'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '31 Aug 2020 14:14'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '97.9' F	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '55'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '126'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '82'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	02 Sep 2020 19:51:44

US3892034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:59

US3892034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:51:59

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

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)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '13:38'	(b) (4) Andryelle Toledo (b) (4)	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '31 Aug 2020 13:38'	System	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Left Arm (LEFT ARM)'	Andryelle Toledo (b) (4)	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'ONCE'	System	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 19:48:06

US3892034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:16

US3892034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:16

US3892034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '13:12'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:16

US3892034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '31 Aug 2020 13:12'	System	02 Sep 2020 19:52:16

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '31 Aug 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '13:05'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '31 Aug 2020 13:05'	System	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered empty.	System	02 Sep 2020 19:52:32

US3892034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	02 Sep 2020 19:52:40

US3892034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '1'	System	02 Sep 2020 19:52:40

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T14:17:08', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8c2efb53-4b81-4c3c-b9b9-0d80373778a1'	System	31 Aug 2020 20:18:02
User entered 'Yes (Y)'	System	31 Aug 2020 20:18:02

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T14:17:26', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8c2efb53-4b81-4c3c-b9b9-0d80373778a1'	System	31 Aug 2020 20:18:02
User entered '97.9'	System	31 Aug 2020 20:18:02

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:17:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8c2efb53-4b81-4c3c-b9b9-0d80373778a1'	System	31 Aug 2020 20:18:02
User entered 'No (N)'	System	31 Aug 2020 20:18:02

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:17:55', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8c2efb53-4b81-4c3c-b9b9-0d80373778a1'	System	31 Aug 2020 20:18:02
User entered '31 Aug 2020 14:17'	System	31 Aug 2020 20:18:02

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 13:58'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 16:28'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T23:56:46', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'defd971d-0514-4c65-9327-c241b5efe8ea'	System	01 Sep 2020 05:57:25
User entered 'Yes (Y)'	System	01 Sep 2020 05:57:25

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T23:57:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'defd971d-0514-4c65-9327-c241b5efe8ea' User entered '96.4'	System	01 Sep 2020 05:57:25
	System	01 Sep 2020 05:57:25

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:57:09', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'defd971d-0514-4c65-9327-c241b5efe8ea'	System	01 Sep 2020 05:57:25
User entered 'No (N)'	System	01 Sep 2020 05:57:25

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:57:20', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'defd971d-0514-4c65-9327-c241b5efe8ea'	System	01 Sep 2020 05:57:25
User entered '31 Aug 2020 23:57'	System	01 Sep 2020 05:57:25

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 17:23'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 2'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T13:09:01', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0343de8b-0a73-4e1a-b7f2-bc233c47b455'	System	01 Sep 2020 19:09:34
User entered 'Yes (Y)'	System	01 Sep 2020 19:09:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T13:09:12', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0343de8b-0a73-4e1a-b7f2-bc233c47b455'	System	01 Sep 2020 19:09:34
User entered '98.3'	System	01 Sep 2020 19:09:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T13:09:19', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0343de8b-0a73-4e1a-b7f2-bc233c47b455'	System	01 Sep 2020 19:09:34
User entered 'No (N)'	System	01 Sep 2020 19:09:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:09:30', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0343de8b-0a73-4e1a-b7f2-bc233c47b455'	System	01 Sep 2020 19:09:34
User entered '01 Sep 2020 13:09'	System	01 Sep 2020 19:09:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 3'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-02T13:27:30', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b411c4d8-f734-4391-8144-a28bc8efd8b0'	System	02 Sep 2020 19:27:57
User entered 'Yes (Y)'	System	02 Sep 2020 19:27:57

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:27:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b411c4d8-f734-4391-8144-a28bc8efd8b0'	System	02 Sep 2020 19:27:57
User entered '96.3'	System	02 Sep 2020 19:27:57

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-02T13:27:45', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b411c4d8-f734-4391-8144-a28bc8efd8b0'	System	02 Sep 2020 19:27:57
User entered 'No (N)'	System	02 Sep 2020 19:27:57

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-02T13:27:54', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b411c4d8-f734-4391-8144-a28bc8efd8b0'	System	02 Sep 2020 19:27:57
User entered '02 Sep 2020 13:27'	System	02 Sep 2020 19:27:57

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 4'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:38:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7c06614c-e219-4292-be94-9501c59f0210'	System	03 Sep 2020 21:39:43
User entered 'Yes (Y)'	System	03 Sep 2020 21:39:43

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:38:57', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7c06614c-e219-4292-be94-9501c59f0210' User entered '97.2'	System	03 Sep 2020 21:39:43

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:39:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7c06614c-e219-4292-be94-9501c59f0210'	System	03 Sep 2020 21:39:43
User entered 'No (N)'	System	03 Sep 2020 21:39:43

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:39:38', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7c06614c-e219-4292-be94-9501c59f0210'	System	03 Sep 2020 21:39:43
User entered '03 Sep 2020 15:39'	System	03 Sep 2020 21:39:43

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 5'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:03:33', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '4c54b55c-9373-4c80-a099-6c05be5f77ea'	System	04 Sep 2020 22:04:34
User entered 'Yes (Y)'	System	04 Sep 2020 22:04:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-04T16:04:16', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '4c54b55c-9373-4c80-a099-6c05be5f77ea' User entered '96.2'	System	04 Sep 2020 22:04:34
	System	04 Sep 2020 22:04:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:04:21', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '4c54b55c-9373-4c80-a099-6c05be5f77ea'	System	04 Sep 2020 22:04:34
User entered 'No (N)'	System	04 Sep 2020 22:04:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:04:30', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '4c54b55c-9373-4c80-a099-6c05be5f77ea'	System	04 Sep 2020 22:04:34
User entered '04 Sep 2020 16:04'	System	04 Sep 2020 22:04:34

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 6'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:08:31', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0b4bd5ae-e342-4c94-841b-ec2dd8f3de1c'	System	05 Sep 2020 23:09:24
User entered 'Yes (Y)'	System	05 Sep 2020 23:09:24

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:09:02', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0b4bd5ae-e342-4c94-841b-ec2dd8f3de1c' User entered '97.1'	System	05 Sep 2020 23:09:24
	System	05 Sep 2020 23:09:24

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:09:08', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0b4bd5ae-e342-4c94-841b-ec2dd8f3de1c'	System	05 Sep 2020 23:09:24
User entered 'No (N)'	System	05 Sep 2020 23:09:24

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:09:21', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0b4bd5ae-e342-4c94-841b-ec2dd8f3de1c'	System	05 Sep 2020 23:09:24
User entered '05 Sep 2020 17:09'	System	05 Sep 2020 23:09:24

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 7'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:47:19', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'fbdbd993-2cc6-45e2-9e2b-955f627a5d37'	System	07 Sep 2020 04:47:47
User entered 'Yes (Y)'	System	07 Sep 2020 04:47:47

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-06T22:47:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'fbdbd993-2cc6-45e2-9e2b-955f627a5d37'	System	07 Sep 2020 04:47:47
User entered '96.9'	System	07 Sep 2020 04:47:47

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:47:35', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'fbdbd993-2cc6-45e2-9e2b-955f627a5d37'	System	07 Sep 2020 04:47:47
User entered 'No (N)'	System	07 Sep 2020 04:47:47

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:47:43', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'fbdbd993-2cc6-45e2-9e2b-955f627a5d37'	System	07 Sep 2020 04:47:47
User entered '06 Sep 2020 22:47'	System	07 Sep 2020 04:47:47

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T14:18:34', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eb338815-6940-4247-a38e-eac20a1a9f53'	System	31 Aug 2020 20:21:24
User entered 'None (1)'	System	31 Aug 2020 20:21:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:18:39', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eb338815-6940-4247-a38e-eac20a1a9f53'	System	31 Aug 2020 20:21:24
User entered 'No (N)'	System	31 Aug 2020 20:21:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:18:43', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eb338815-6940-4247-a38e-eac20a1a9f53'	System	31 Aug 2020 20:21:24
User entered 'No (N)'	System	31 Aug 2020 20:21:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:18:49', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eb338815-6940-4247-a38e-eac20a1a9f53'	System	31 Aug 2020 20:21:24
User entered 'None (1)'	System	31 Aug 2020 20:21:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T14:19:31', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eb338815-6940-4247-a38e-eac20a1a9f53'	System	31 Aug 2020 20:21:24
User entered '31 Aug 2020 14:19'	System	31 Aug 2020 20:21:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 13:58'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 16:28'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:59:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f2835db6-0f34-4262-8813-9bf4ba4ccc45'	System	01 Sep 2020 05:59:31
User entered 'None (1)'	System	01 Sep 2020 05:59:31

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:59:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f2835db6-0f34-4262-8813-9bf4ba4ccc45'	System	01 Sep 2020 05:59:31
User entered 'No (N)'	System	01 Sep 2020 05:59:31

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:59:12', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f2835db6-0f34-4262-8813-9bf4ba4ccc45'	System	01 Sep 2020 05:59:31
User entered 'No (N)'	System	01 Sep 2020 05:59:31

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:59:22', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f2835db6-0f34-4262-8813-9bf4ba4ccc45'	System	01 Sep 2020 05:59:31
User entered 'None (1)'	System	01 Sep 2020 05:59:31

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:59:26', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f2835db6-0f34-4262-8813-9bf4ba4ccc45'	System	01 Sep 2020 05:59:31
User entered '31 Aug 2020 23:59'	System	01 Sep 2020 05:59:31

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 17:23'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 2'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:09:47', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '1e036f58-cbe3-4a89-a559-9a9a45022018'	System	01 Sep 2020 19:10:22
User entered 'None (1)'	System	01 Sep 2020 19:10:22

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:09:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '1e036f58-cbe3-4a89-a559-9a9a45022018'	System	01 Sep 2020 19:10:22
User entered 'No (N)'	System	01 Sep 2020 19:10:22

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:10:01', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '1e036f58-cbe3-4a89-a559-9a9a45022018'	System	01 Sep 2020 19:10:22
User entered 'No (N)'	System	01 Sep 2020 19:10:22

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:10:09', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '1e036f58-cbe3-4a89-a559-9a9a45022018'	System	01 Sep 2020 19:10:22
User entered 'None (1)'	System	01 Sep 2020 19:10:22

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:10:17', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '1e036f58-cbe3-4a89-a559-9a9a45022018'	System	01 Sep 2020 19:10:22
User entered '01 Sep 2020 13:10'	System	01 Sep 2020 19:10:22

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 3'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:28:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '091adde4-db66-4b6d-b853-93896a22da0c'	System	02 Sep 2020 19:28:43
User entered 'None (1)'	System	02 Sep 2020 19:28:43

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:28:12', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '091adde4-db66-4b6d-b853-93896a22da0c'	System	02 Sep 2020 19:28:43
User entered 'No (N)'	System	02 Sep 2020 19:28:43

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-02T13:28:23', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '091adde4-db66-4b6d-b853-93896a22da0c'	System	02 Sep 2020 19:28:43
User entered 'No (N)'	System	02 Sep 2020 19:28:43

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:28:32', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '091adde4-db66-4b6d-b853-93896a22da0c'	System	02 Sep 2020 19:28:43
User entered 'None (1)'	System	02 Sep 2020 19:28:43

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-02T13:28:38', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '091adde4-db66-4b6d-b853-93896a22da0c'	System	02 Sep 2020 19:28:43
User entered '02 Sep 2020 13:28'	System	02 Sep 2020 19:28:43

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 4'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-03T15:39:45', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '135a8bf3-9d89-4f8e-b218-7c79b39592b2'	System	03 Sep 2020 21:40:24
User entered 'None (1)'	System	03 Sep 2020 21:40:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-03T15:39:50', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '135a8bf3-9d89-4f8e-b218-7c79b39592b2'	System	03 Sep 2020 21:40:24
User entered 'No (N)'	System	03 Sep 2020 21:40:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:40:04', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '135a8bf3-9d89-4f8e-b218-7c79b39592b2'	System	03 Sep 2020 21:40:24
User entered 'No (N)'	System	03 Sep 2020 21:40:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-03T15:40:12', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '135a8bf3-9d89-4f8e-b218-7c79b39592b2'	System	03 Sep 2020 21:40:24
User entered 'None (1)'	System	03 Sep 2020 21:40:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:40:21', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '135a8bf3-9d89-4f8e-b218-7c79b39592b2'	System	03 Sep 2020 21:40:24
User entered '03 Sep 2020 15:40'	System	03 Sep 2020 21:40:24

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 5'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:04:42', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a9d8c03b-a377-44fe-9397-960be8dbe58e'	System	04 Sep 2020 22:05:08
User entered 'None (1)'	System	04 Sep 2020 22:05:08

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:04:47', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a9d8c03b-a377-44fe-9397-960be8dbe58e'	System	04 Sep 2020 22:05:08
User entered 'No (N)'	System	04 Sep 2020 22:05:08

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:04:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a9d8c03b-a377-44fe-9397-960be8dbe58e'	System	04 Sep 2020 22:05:08
User entered 'No (N)'	System	04 Sep 2020 22:05:08

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:04:57', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a9d8c03b-a377-44fe-9397-960be8dbe58e'	System	04 Sep 2020 22:05:08
User entered 'None (1)'	System	04 Sep 2020 22:05:08

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:02', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a9d8c03b-a377-44fe-9397-960be8dbe58e'	System	04 Sep 2020 22:05:08
User entered '04 Sep 2020 16:05'	System	04 Sep 2020 22:05:08

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 6'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:09:37', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9f79ae2f-276c-448c-8810-b766182fe355'	System	05 Sep 2020 23:10:48
User entered 'None (1)'	System	05 Sep 2020 23:10:48

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:09:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9f79ae2f-276c-448c-8810-b766182fe355'	System	05 Sep 2020 23:10:48
User entered 'No (N)'	System	05 Sep 2020 23:10:48

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-05T17:09:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9f79ae2f-276c-448c-8810-b766182fe355'	System	05 Sep 2020 23:10:48
User entered 'No (N)'	System	05 Sep 2020 23:10:48

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-05T17:09:58', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9f79ae2f-276c-448c-8810-b766182fe355'	System	05 Sep 2020 23:10:48
User entered 'None (1)'	System	05 Sep 2020 23:10:48

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-05T17:10:45', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9f79ae2f-276c-448c-8810-b766182fe355'	System	05 Sep 2020 23:10:48
User entered '05 Sep 2020 17:10'	System	05 Sep 2020 23:10:48

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 7'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-06T22:47:49', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ee87f06d-b79b-4f18-a621-05c675e43fb9'	System	07 Sep 2020 04:48:33
User entered 'None (1)'	System	07 Sep 2020 04:48:33

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:47:53', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ee87f06d-b79b-4f18-a621-05c675e43fb9'	System	07 Sep 2020 04:48:33
User entered 'No (N)'	System	07 Sep 2020 04:48:33

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:48:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ee87f06d-b79b-4f18-a621-05c675e43fb9'	System	07 Sep 2020 04:48:33
User entered 'No (N)'	System	07 Sep 2020 04:48:33

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-06T22:48:25', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ee87f06d-b79b-4f18-a621-05c675e43fb9'	System	07 Sep 2020 04:48:33
User entered 'None (1)'	System	07 Sep 2020 04:48:33

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:48:30', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ee87f06d-b79b-4f18-a621-05c675e43fb9'	System	07 Sep 2020 04:48:33
User entered '06 Sep 2020 22:48'	System	07 Sep 2020 04:48:33

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:19:39', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d'	System	31 Aug 2020 20:21:49
User entered 'None (0)'	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:19:53', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d'	System	31 Aug 2020 20:21:49
User entered 'None (0)'	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:20:17', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d'	System	31 Aug 2020 20:21:49
User entered 'None (0)'	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:20:24', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d' User entered 'None (0)'	System	31 Aug 2020 20:21:49
	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T14:20:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d'	System	31 Aug 2020 20:21:49
User entered 'None (0)'	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:20:33', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d'	System	31 Aug 2020 20:21:49
User entered 'None (0)'	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:20:57', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d'	System	31 Aug 2020 20:21:49
User entered 'No (N)'	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T14:21:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ffb7159d-7bb8-4a1e-8627-165b760cf08d'	System	31 Aug 2020 20:21:49
User entered '31 Aug 2020 14:21'	System	31 Aug 2020 20:21:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 13:58'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 16:28'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-08-31T23:59:41', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b'	System	01 Sep 2020 06:00:43
User entered 'None (0)'	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:59:48', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b'	System	01 Sep 2020 06:00:43
User entered 'None (0)'	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-08-31T23:59:56', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b'	System	01 Sep 2020 06:00:43
User entered 'None (0)'	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T00:00:01', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b' User entered 'None (0)'	System	01 Sep 2020 06:00:43
	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T00:00:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b'	System	01 Sep 2020 06:00:43
User entered 'None (0)'	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T00:00:25', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b'	System	01 Sep 2020 06:00:43
User entered 'None (0)'	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T00:00:34', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b'	System	01 Sep 2020 06:00:43
User entered 'No (N)'	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T00:00:38', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36c31298-5132-4748-8df8-d6458263da3b'	System	01 Sep 2020 06:00:43
User entered '01 Sep 2020 00:00'	System	01 Sep 2020 06:00:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '31 Aug 2020 17:23'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 2'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T13:10:26', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered 'None (0)'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T13:10:31', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered 'None (0)'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T13:10:37', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered 'None (0)'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:10:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered 'None (0)'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-01T13:10:48', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered 'None (0)'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:11:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered 'None (0)'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:11:09', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered 'No (N)'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-01T13:11:14', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '9425eef6-e84d-4cd9-96c8-dd4a27cc5520'	System	01 Sep 2020 19:11:19
User entered '01 Sep 2020 13:11'	System	01 Sep 2020 19:11:19

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 3'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:28:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered 'None (0)'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:28:58', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered 'None (0)'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:29:03', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered 'None (0)'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:29:10', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered 'None (0)'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:29:13', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered 'None (0)'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:29:18', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered 'None (0)'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-02T13:29:34', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered 'No (N)'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-02T13:29:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '762c8922-2fe0-4e7c-a4d7-741f68f7030e'	System	02 Sep 2020 19:29:43
User entered '02 Sep 2020 13:29'	System	02 Sep 2020 19:29:43

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 4'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:40:30', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9'	System	03 Sep 2020 21:41:49
User entered 'None (0)'	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-03T15:40:34', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9'	System	03 Sep 2020 21:41:49
User entered 'None (0)'	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:40:39', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9'	System	03 Sep 2020 21:41:49
User entered 'None (0)'	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:40:45', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9'	System	03 Sep 2020 21:41:49
User entered 'None (0)'	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:40:49', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9' User entered 'None (0)'	System	03 Sep 2020 21:41:49
	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-03T15:40:53', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9'	System	03 Sep 2020 21:41:49
User entered 'None (0)'	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:41:37', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9'	System	03 Sep 2020 21:41:49
User entered 'No (N)'	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-03T15:41:46', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '664a628b-0747-4f3d-a229-4e750a84b8c9'	System	03 Sep 2020 21:41:49
User entered '03 Sep 2020 15:41'	System	03 Sep 2020 21:41:49

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 5'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:11', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered 'None (0)'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:15', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered 'None (0)'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:20', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered 'None (0)'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:25', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered 'None (0)'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:28', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered 'None (0)'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:32', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered 'None (0)'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:38', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered 'No (N)'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-04T16:05:42', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '26485b8e-9426-4995-a9cc-6a4821fa5a95'	System	04 Sep 2020 22:05:45
User entered '04 Sep 2020 16:05'	System	04 Sep 2020 22:05:45

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 6'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-05T17:10:53', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered 'None (0)'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-05T17:11:10', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered 'None (0)'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:19:56', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered 'None (0)'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:20:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered 'None (0)'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:20:04', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered 'None (0)'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-05T17:20:09', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered 'None (0)'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-05T17:20:16', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered 'No (N)'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-05T17:20:21', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'dfa2ae7b-c3ab-4ec5-b211-04fd180bca25'	System	05 Sep 2020 23:20:24
User entered '05 Sep 2020 17:20'	System	05 Sep 2020 23:20:24

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 7'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:48:38', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered 'None (0)'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-06T22:48:43', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered 'None (0)'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:48:49', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered 'None (0)'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-06T22:48:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered 'None (0)'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:48:56', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered 'None (0)'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:48:59', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered 'None (0)'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-06T22:49:03', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered 'No (N)'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-06T22:49:10', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'efb38f62-694e-4dd8-8253-fa17626b37b3'	System	07 Sep 2020 04:49:12
User entered '06 Sep 2020 22:49'	System	07 Sep 2020 04:49:12

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:48:06

US3892034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	09 Sep 2020 20:57:06

US3892034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '9 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	09 Sep 2020 20:57:06

US3892034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	09 Sep 2020 20:57:06

US3892034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	09 Sep 2020 20:57:06
	(b) (4)	

US3892034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	09 Sep 2020 20:58:24

US3892034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User entered '1'	System	09 Sep 2020 20:58:24

US3892034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	16 Sep 2020 19:26:41

US3892034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '16 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 19:26:41

US3892034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 19:26:41

US3892034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 19:26:41

US3892034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 19:26:46

US3892034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User entered '1'	System	16 Sep 2020 19:26:46

US3892034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:27:45

US3892034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '21 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:27:45

US3892034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:27:45

US3892034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:27:45

US3892034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	21 Sep 2020 23:27:50

US3892034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User entered '1'	System	21 Sep 2020 23:27:50

US3892034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:13:26

US3892034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '28 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:13:26

US3892034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Home (Home)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:13:26

US3892034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'VISIT2'	System	28 Sep 2020 18:13:26

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4) (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '11:08'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '28 Sep 2020 11:08'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '97.9' F	Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '75'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '14'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '122'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '78'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:21:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '12:46'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '28 Sep 2020 12:46'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '97.7' F	Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '65'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '126'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '74'	(b) (4) Andryelle Toledo (b) (4)	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	30 Sep 2020 22:06:47

US3892034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:13:46

US3892034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '28 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:13:46

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

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)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '28 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '12:07'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '28 Sep 2020 12:07'	System	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Left Arm (LEFT ARM)'	Stefanie Vasconez (b) (4)	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'ONCE'	System	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:21:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 18:14:08

US3892034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:15:42

US3892034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '28 Sep 2020'	Stefanie Vasconez (b) (4)	28 Sep 2020 18:15:42

US3892034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '11:20'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:15:42

US3892034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '28 Sep 2020 11:20'	System	28 Sep 2020 18:15:42

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '28 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stefanie Vasconez (b) (4) (b) (4)	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '11:27'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '28 Sep 2020 11:27'	System	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stefanie Vasconez (b) (4) (b) (4)	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'No (N)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered empty.	System	28 Sep 2020 18:16:05

US3892034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	28 Sep 2020 18:16:10

US3892034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '1'	System	28 Sep 2020 18:16:10

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:42:16', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7f586c77-5821-4ec9-b646-282ab9fa4b5d'	System	28 Sep 2020 18:42:54
User entered 'Yes (Y)'	System	28 Sep 2020 18:42:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-28T12:42:26', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7f586c77-5821-4ec9-b646-282ab9fa4b5d'	System	28 Sep 2020 18:42:54
User entered '97.7'	System	28 Sep 2020 18:42:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:42:33', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7f586c77-5821-4ec9-b646-282ab9fa4b5d'	System	28 Sep 2020 18:42:54
User entered 'No (N)'	System	28 Sep 2020 18:42:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-28T12:42:49', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7f586c77-5821-4ec9-b646-282ab9fa4b5d'	System	28 Sep 2020 18:42:54
User entered '28 Sep 2020 12:42'	System	28 Sep 2020 18:42:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 12:27'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 14:57'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:46:10', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68d4fcf5-b178-43ab-87b3-85229ef85787'	System	29 Sep 2020 16:46:40
User entered 'Yes (Y)'	System	29 Sep 2020 16:46:40

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-29T10:46:19', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68d4fcf5-b178-43ab-87b3-85229ef85787' User entered '97.3'	System	29 Sep 2020 16:46:40
	System	29 Sep 2020 16:46:40

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-29T10:46:25', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68d4fcf5-b178-43ab-87b3-85229ef85787'	System	29 Sep 2020 16:46:40
User entered 'No (N)'	System	29 Sep 2020 16:46:40

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:46:35', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68d4fcf5-b178-43ab-87b3-85229ef85787'	System	29 Sep 2020 16:46:40
User entered '29 Sep 2020 10:46'	System	29 Sep 2020 16:46:40

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 15:52'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 2'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-30T09:32:24', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '24d567ef-d925-40eb-871d-f934c80021a8'	System	30 Sep 2020 15:33:02
User entered 'Yes (Y)'	System	30 Sep 2020 15:33:02

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:32:47', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '24d567ef-d925-40eb-871d-f934c80021a8'	System	30 Sep 2020 15:33:02
User entered '95.9'	System	30 Sep 2020 15:33:02

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:32:53', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '24d567ef-d925-40eb-871d-f934c80021a8'	System	30 Sep 2020 15:33:02
User entered 'No (N)'	System	30 Sep 2020 15:33:02

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:32:58', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '24d567ef-d925-40eb-871d-f934c80021a8'	System	30 Sep 2020 15:33:02
User entered '30 Sep 2020 09:32'	System	30 Sep 2020 15:33:02

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 3'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-01T09:39:36', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0f2bcb80-71d3-4f69-be1b-8fe45dc6b662'	System	01 Oct 2020 15:40:03
User entered 'Yes (Y)'	System	01 Oct 2020 15:40:03

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-01T09:39:48', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0f2bcb80-71d3-4f69-be1b-8fe45dc6b662'	System	01 Oct 2020 15:40:03
User entered '98.6'	System	01 Oct 2020 15:40:03

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-01T09:39:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0f2bcb80-71d3-4f69-be1b-8fe45dc6b662'	System	01 Oct 2020 15:40:03
User entered 'No (N)'	System	01 Oct 2020 15:40:03

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:40:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0f2bcb80-71d3-4f69-be1b-8fe45dc6b662'	System	01 Oct 2020 15:40:03
User entered '01 Oct 2020 09:40'	System	01 Oct 2020 15:40:03

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 4'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:29:38', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b1d35398-7e4f-411b-b93f-32f95038a46e'	System	02 Oct 2020 17:30:05
User entered 'Yes (Y)'	System	02 Oct 2020 17:30:05

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:29:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b1d35398-7e4f-411b-b93f-32f95038a46e'	System	02 Oct 2020 17:30:05
User entered '97.1'	System	02 Oct 2020 17:30:05

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:29:56', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b1d35398-7e4f-411b-b93f-32f95038a46e'	System	02 Oct 2020 17:30:05
User entered 'No (N)'	System	02 Oct 2020 17:30:05

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:30:01', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b1d35398-7e4f-411b-b93f-32f95038a46e'	System	02 Oct 2020 17:30:05
User entered '02 Oct 2020 11:30'	System	02 Oct 2020 17:30:05

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 5'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 6'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:04:20', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a3c57fee-4e8f-4423-9dac-c9b9bf416fd6'	System	04 Oct 2020 16:04:54
User entered 'Yes (Y)'	System	04 Oct 2020 16:04:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:04:37', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a3c57fee-4e8f-4423-9dac-c9b9bf416fd6'	System	04 Oct 2020 16:04:54
User entered '97.2'	System	04 Oct 2020 16:04:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:04:42', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a3c57fee-4e8f-4423-9dac-c9b9bf416fd6'	System	04 Oct 2020 16:04:54
User entered 'No (N)'	System	04 Oct 2020 16:04:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:04:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a3c57fee-4e8f-4423-9dac-c9b9bf416fd6'	System	04 Oct 2020 16:04:54
User entered '04 Oct 2020 10:04'	System	04 Oct 2020 16:04:54

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 7'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-05T11:13:27', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '16436ce2-b5bd-4b09-82bb-1cfcfb8fbee'	System	05 Oct 2020 17:13:51
User entered 'Yes (Y)'	System	05 Oct 2020 17:13:51

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-05T11:13:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '16436ce2-b5bd-4b09-82bb-1cfcfb8fbee'	System	05 Oct 2020 17:13:51
User entered '97.3'	System	05 Oct 2020 17:13:51

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-05T11:13:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '16436ce2-b5bd-4b09-82bb-1cfcfb8fbee'	System	05 Oct 2020 17:13:51
User entered 'No (N)'	System	05 Oct 2020 17:13:51

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:13:48', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '16436ce2-b5bd-4b09-82bb-1cfcfb8fbee'	System	05 Oct 2020 17:13:51
User entered '05 Oct 2020 11:13'	System	05 Oct 2020 17:13:51

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:43:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'daf8c3b8-0001-40ce-a8d1-e550b8eb94d6'	System	28 Sep 2020 18:43:37
User entered 'None (1)'	System	28 Sep 2020 18:43:37

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-28T12:43:12', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'daf8c3b8-0001-40ce-a8d1-e550b8eb94d6'	System	28 Sep 2020 18:43:37
User entered 'No (N)'	System	28 Sep 2020 18:43:37

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-28T12:43:18', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'daf8c3b8-0001-40ce-a8d1-e550b8eb94d6'	System	28 Sep 2020 18:43:37
User entered 'No (N)'	System	28 Sep 2020 18:43:37

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:43:26', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'daf8c3b8-0001-40ce-a8d1-e550b8eb94d6'	System	28 Sep 2020 18:43:37
User entered 'None (1)'	System	28 Sep 2020 18:43:37

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:43:34', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'daf8c3b8-0001-40ce-a8d1-e550b8eb94d6'	System	28 Sep 2020 18:43:37
User entered '28 Sep 2020 12:43'	System	28 Sep 2020 18:43:37

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 12:27'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 14:57'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:46:45', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '04e54101-aaa1-4c05-beb5-2cb51fc8d0ec'	System	29 Sep 2020 16:47:18
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 16:47:18

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:46:51', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '04e54101-aaa1-4c05-beb5-2cb51fc8d0ec'	System	29 Sep 2020 16:47:18
User entered 'No (N)'	System	29 Sep 2020 16:47:18

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:46:56', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '04e54101-aaa1-4c05-beb5-2cb51fc8d0ec'	System	29 Sep 2020 16:47:18
User entered 'No (N)'	System	29 Sep 2020 16:47:18

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:02', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '04e54101-aaa1-4c05-beb5-2cb51fc8d0ec'	System	29 Sep 2020 16:47:18
User entered 'None (1)'	System	29 Sep 2020 16:47:18

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:16', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '04e54101-aaa1-4c05-beb5-2cb51fc8d0ec'	System	29 Sep 2020 16:47:18
User entered '29 Sep 2020 10:47'	System	29 Sep 2020 16:47:18

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 15:52'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 2'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:04', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '3d3a627c-8587-4ee6-868b-3400b946204b'	System	30 Sep 2020 15:33:27
User entered 'None (1)'	System	30 Sep 2020 15:33:27

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:09', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '3d3a627c-8587-4ee6-868b-3400b946204b'	System	30 Sep 2020 15:33:27
User entered 'No (N)'	System	30 Sep 2020 15:33:27

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:13', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '3d3a627c-8587-4ee6-868b-3400b946204b'	System	30 Sep 2020 15:33:27
User entered 'No (N)'	System	30 Sep 2020 15:33:27

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:18', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '3d3a627c-8587-4ee6-868b-3400b946204b'	System	30 Sep 2020 15:33:27
User entered 'None (1)'	System	30 Sep 2020 15:33:27

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:24', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '3d3a627c-8587-4ee6-868b-3400b946204b'	System	30 Sep 2020 15:33:27
User entered '30 Sep 2020 09:33'	System	30 Sep 2020 15:33:27

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 3'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:40:10', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ae44e835-cdc3-4952-8d89-9c51a5c6b280'	System	01 Oct 2020 15:40:34
User entered 'None (1)'	System	01 Oct 2020 15:40:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:40:14', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ae44e835-cdc3-4952-8d89-9c51a5c6b280'	System	01 Oct 2020 15:40:34
User entered 'No (N)'	System	01 Oct 2020 15:40:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:40:20', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ae44e835-cdc3-4952-8d89-9c51a5c6b280'	System	01 Oct 2020 15:40:34
User entered 'No (N)'	System	01 Oct 2020 15:40:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:40:24', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ae44e835-cdc3-4952-8d89-9c51a5c6b280'	System	01 Oct 2020 15:40:34
User entered 'None (1)'	System	01 Oct 2020 15:40:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:40:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ae44e835-cdc3-4952-8d89-9c51a5c6b280'	System	01 Oct 2020 15:40:34
User entered '01 Oct 2020 09:40'	System	01 Oct 2020 15:40:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 4'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:30:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a30e74c4-c48c-4875-ac6e-b74fba36c2c0'	System	02 Oct 2020 17:30:34
User entered 'None (1)'	System	02 Oct 2020 17:30:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:30:11', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a30e74c4-c48c-4875-ac6e-b74fba36c2c0'	System	02 Oct 2020 17:30:34
User entered 'No (N)'	System	02 Oct 2020 17:30:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:30:15', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a30e74c4-c48c-4875-ac6e-b74fba36c2c0'	System	02 Oct 2020 17:30:34
User entered 'No (N)'	System	02 Oct 2020 17:30:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:30:19', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a30e74c4-c48c-4875-ac6e-b74fba36c2c0'	System	02 Oct 2020 17:30:34
User entered 'None (1)'	System	02 Oct 2020 17:30:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:30:26', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'a30e74c4-c48c-4875-ac6e-b74fba36c2c0'	System	02 Oct 2020 17:30:34
User entered '02 Oct 2020 11:30'	System	02 Oct 2020 17:30:34

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 5'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 6'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:05:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8126c41b-437f-4c7c-87c1-3450aa833714'	System	04 Oct 2020 16:05:25
User entered 'None (1)'	System	04 Oct 2020 16:05:25

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:05:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8126c41b-437f-4c7c-87c1-3450aa833714'	System	04 Oct 2020 16:05:25
User entered 'No (N)'	System	04 Oct 2020 16:05:25

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:05:12', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8126c41b-437f-4c7c-87c1-3450aa833714'	System	04 Oct 2020 16:05:25
User entered 'No (N)'	System	04 Oct 2020 16:05:25

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:05:15', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8126c41b-437f-4c7c-87c1-3450aa833714'	System	04 Oct 2020 16:05:25
User entered 'None (1)'	System	04 Oct 2020 16:05:25

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:05:22', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '8126c41b-437f-4c7c-87c1-3450aa833714'	System	04 Oct 2020 16:05:25
User entered '04 Oct 2020 10:05'	System	04 Oct 2020 16:05:25

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 7'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-05T11:13:55', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7072a841-ca5b-44d7-bff0-832d01ef6e96'	System	05 Oct 2020 17:14:12
User entered 'None (1)'	System	05 Oct 2020 17:14:12

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:13:59', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7072a841-ca5b-44d7-bff0-832d01ef6e96'	System	05 Oct 2020 17:14:12
User entered 'No (N)'	System	05 Oct 2020 17:14:12

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:02', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7072a841-ca5b-44d7-bff0-832d01ef6e96'	System	05 Oct 2020 17:14:12
User entered 'No (N)'	System	05 Oct 2020 17:14:12

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7072a841-ca5b-44d7-bff0-832d01ef6e96'	System	05 Oct 2020 17:14:12
User entered 'None (1)'	System	05 Oct 2020 17:14:12

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:09', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7072a841-ca5b-44d7-bff0-832d01ef6e96'	System	05 Oct 2020 17:14:12
User entered '05 Oct 2020 11:14'	System	05 Oct 2020 17:14:12

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-28T12:43:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered 'None (0)'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:43:55', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered 'None (0)'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:44:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered 'None (0)'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:44:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered 'None (0)'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-28T12:44:11', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered 'None (0)'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:44:16', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered 'None (0)'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:44:27', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered 'No (N)'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-28T12:44:31', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2c2e5821-a155-4f00-a67a-91f9eed47d0'	System	28 Sep 2020 18:44:36
User entered '28 Sep 2020 12:44'	System	28 Sep 2020 18:44:36

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 12:27'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 14:57'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:25', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered 'None (0)'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:30', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered 'No interference with activity (1)'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:35', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered 'None (0)'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered 'None (0)'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:51', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered 'None (0)'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:47:58', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered 'None (0)'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-29T10:48:02', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered 'No (N)'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-29T10:48:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '94e21882-4dd7-4d95-9656-6671e815a2b4'	System	29 Sep 2020 16:48:13
User entered '29 Sep 2020 10:48'	System	29 Sep 2020 16:48:13

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '28 Sep 2020 15:52'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 2'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:34', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7' User entered 'None (0)'	System	30 Sep 2020 15:34:15
	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-30T09:33:46', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7' User entered 'None (0)'	System	30 Sep 2020 15:34:15
	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:50', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7' User entered 'None (0)'	System	30 Sep 2020 15:34:15
	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:54', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7' User entered 'None (0)'	System	30 Sep 2020 15:34:15
	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:33:57', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7' User entered 'None (0)'	System	30 Sep 2020 15:34:15
	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:34:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7' User entered 'None (0)'	System	30 Sep 2020 15:34:15
	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-09-30T09:34:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7'	System	30 Sep 2020 15:34:15
User entered 'No (N)'	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-09-30T09:34:12', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '36a11c64-9af9-4025-8567-0414172cacc7'	System	30 Sep 2020 15:34:15
User entered '30 Sep 2020 09:34'	System	30 Sep 2020 15:34:15

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 3'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-01T09:40:50', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81'	System	01 Oct 2020 15:41:25
User entered 'None (0)'	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:40:56', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81'	System	01 Oct 2020 15:41:25
User entered 'No interference with activity (1)'	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:41:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81' User entered 'None (0)'	System	01 Oct 2020 15:41:25
	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:41:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81' User entered 'None (0)'	System	01 Oct 2020 15:41:25
	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-01T09:41:09', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81' User entered 'None (0)'	System	01 Oct 2020 15:41:25
	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:41:13', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81'	System	01 Oct 2020 15:41:25
User entered 'None (0)'	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-01T09:41:18', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81'	System	01 Oct 2020 15:41:25
User entered 'No (N)'	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-01T09:41:22', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '61855e1a-335c-4d0d-9c8d-1cd290743a81'	System	01 Oct 2020 15:41:25
User entered '01 Oct 2020 09:41'	System	01 Oct 2020 15:41:25

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 4'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:30:50', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered 'None (0)'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:30:58', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered 'None (0)'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:31:18', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered 'None (0)'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:31:23', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered 'None (0)'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:31:26', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered 'None (0)'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:31:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered 'None (0)'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-02T11:31:35', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered 'No (N)'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-02T11:31:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0d696d09-d04e-4f8c-a390-ec04dcdd4693'	System	02 Oct 2020 17:31:44
User entered '02 Oct 2020 11:31'	System	02 Oct 2020 17:31:44

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 5'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 6'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:05:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered 'None (0)'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:05:31', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered 'None (0)'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:05:53', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered 'None (0)'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:05:57', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered 'None (0)'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered 'None (0)'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:06:10', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered 'None (0)'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-04T10:22:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered 'No (N)'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-10-04T10:22:50', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '68ddd29b-52e8-45b9-933d-b6ced4a1d7ec'	System	04 Oct 2020 16:22:54
User entered '04 Oct 2020 10:22'	System	04 Oct 2020 16:22:54

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	28 Sep 2020 18:14:08
User entered 'Day 7'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:16', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered 'None (0)'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:18', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered 'None (0)'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:21', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered 'None (0)'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:24', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered 'None (0)'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:27', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered 'None (0)'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered 'None (0)'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:34', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered 'No (N)'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-05T11:14:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'f5dff443-be82-4474-ba1f-236c0b3eea83'	System	05 Oct 2020 17:14:43
User entered '05 Oct 2020 11:14'	System	05 Oct 2020 17:14:43

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:14:08

US3892034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:21:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:14:08

US3892034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:38:54

US3892034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:38:54

US3892034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:38:54

US3892034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:38:54

US3892034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:38:59

US3892034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User entered '1'	System	06 Oct 2020 15:38:59

US3892034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:02:06

US3892034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:02:06

US3892034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:02:06

US3892034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:02:06

US3892034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 15:44:39

US3892034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User entered '1'	System	13 Oct 2020 15:44:39

US3892034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	19 Oct 2020 21:37:07

US3892034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '19 Oct 2020'	(b) (4) chase Carnahan (b) (4)	19 Oct 2020 21:37:07

US3892034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) chase Carnahan (b) (4)	19 Oct 2020 21:37:07

US3892034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) chase Carnahan (b) (4)	19 Oct 2020 21:37:07

US3892034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	19 Oct 2020 21:36:53

US3892034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User entered '1'	System	19 Oct 2020 21:36:53

US3892034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:12

US3892034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:12

US3892034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	26 Oct 2020 19:53:12

US3892034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'VISIT3'	System	26 Oct 2020 19:53:12

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '10:59'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '26 Oct 2020 10:59'	System	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '97.1' F	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '59'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'bpm'	System	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'breaths/min'	System	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '122'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '79'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered 'mmHg'	System	26 Oct 2020 19:53:42

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35

US3892034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35

US3892034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:49

US3892034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:53:49

US3892034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:54:05

US3892034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '26 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:54:05

US3892034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '11:12'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:54:05

US3892034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '26 Oct 2020 11:12'	System	26 Oct 2020 19:54:05

US3892034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	26 Oct 2020 19:54:09

US3892034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:35
User entered '1'	System	26 Oct 2020 19:54:09

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 64'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-31T17:34:02', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '5dc419ba-2d6f-4860-af43-827335acabea'	System	31 Oct 2020 23:34:19
User entered 'No (N)'	System	31 Oct 2020 23:34:19

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-31T17:34:11', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '5dc419ba-2d6f-4860-af43-827335acabea'	System	31 Oct 2020 23:34:19
User entered 'No (N)'	System	31 Oct 2020 23:34:19

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-10-31T17:34:17', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '5dc419ba-2d6f-4860-af43-827335acabea' User entered '31 Oct 2020 17:34:17'	System	31 Oct 2020 23:34:19
	System	31 Oct 2020 23:34:19

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 71'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-11-11T18:45:33', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'cffa8c88-237b-407d-bee4-f8e6d4d79bad'	System	12 Nov 2020 01:45:49
User entered 'No (N)'	System	12 Nov 2020 01:45:49

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-11-11T18:45:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'cffa8c88-237b-407d-bee4-f8e6d4d79bad'	System	12 Nov 2020 01:45:49
User entered 'No (N)'	System	12 Nov 2020 01:45:49

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-11-11T18:45:46', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'cffa8c88-237b-407d-bee4-f8e6d4d79bad'	System	12 Nov 2020 01:45:49
User entered '11 Nov 2020 18:45:46'	System	12 Nov 2020 01:45:49

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered 'Day 78'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-11-14T16:22:54', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '958c37e8-78d6-4d80-88d9-1a07bb1a5abd'	System	14 Nov 2020 23:23:15
User entered 'No (N)'	System	14 Nov 2020 23:23:15

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-11-14T16:23:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '958c37e8-78d6-4d80-88d9-1a07bb1a5abd'	System	14 Nov 2020 23:23:15
User entered 'No (N)'	System	14 Nov 2020 23:23:15

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-11-14T16:23:11', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '958c37e8-78d6-4d80-88d9-1a07bb1a5abd'	System	14 Nov 2020 23:23:15
User entered '14 Nov 2020 16:23:11'	System	14 Nov 2020 23:23:15

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 19:48:06

US3892034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:21:55
Data entry locked.	System	31 Aug 2020 19:48:06
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 19:48:06

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 (92211691bcd399a)', Time: '2020-11-21T22:00:43', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'e82e2b3e-4d9f-48e0-95aa-d2cbd2098025'	System	22 Nov 2020 05:00:58
User entered 'No (N)'	System	22 Nov 2020 05:00:58

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2020-11-21T22:00:50', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'e82e2b3e-4d9f-48e0-95aa-d2cbd2098025'	System	22 Nov 2020 05:00:58
User entered 'No (N)'	System	22 Nov 2020 05:00:58

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-11-21T22:00:55', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'e82e2b3e-4d9f-48e0-95aa-d2cbd2098025'	System	22 Nov 2020 05:00:58
User entered '21 Nov 2020 22:00:55'	System	22 Nov 2020 05:00:58

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2020-11-27T13:30:44', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7f59cc5b-21e5-4379-ad09-2c6b2c75e575'	System	27 Nov 2020 20:31:11
User entered 'No (N)'	System	27 Nov 2020 20:31:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2020-11-27T13:30:55', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7f59cc5b-21e5-4379-ad09-2c6b2c75e575'	System	27 Nov 2020 20:31:11
User entered 'No (N)'	System	27 Nov 2020 20:31:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-11-27T13:31:06', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7f59cc5b-21e5-4379-ad09-2c6b2c75e575'	System	27 Nov 2020 20:31:11
User entered '27 Nov 2020 13:31:06'	System	27 Nov 2020 20:31:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2020-12-05T14:04:38', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '06c6be78-4e9b-40f9-882b-2f14426a2b3e'	System	05 Dec 2020 21:04:58
User entered 'No (N)'	System	05 Dec 2020 21:04:58

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2020-12-05T14:04:47', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '06c6be78-4e9b-40f9-882b-2f14426a2b3e'	System	05 Dec 2020 21:04:58
User entered 'No (N)'	System	05 Dec 2020 21:04:58

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-12-05T14:04:54', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '06c6be78-4e9b-40f9-882b-2f14426a2b3e' User entered '05 Dec 2020 14:04:54'	System	05 Dec 2020 21:04:58
	System	05 Dec 2020 21:04:58

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2020-12-09T09:12:35', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '13842abe-86f9-4d04-b864-1d8472b2423d'	System	09 Dec 2020 16:12:55
User entered 'No (N)'	System	09 Dec 2020 16:12:55

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2020-12-09T09:12:46', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '13842abe-86f9-4d04-b864-1d8472b2423d'	System	09 Dec 2020 16:12:55
User entered 'No (N)'	System	09 Dec 2020 16:12:55

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-12-09T09:12:52', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '13842abe-86f9-4d04-b864-1d8472b2423d' User entered '09 Dec 2020 09:12:52'	System	09 Dec 2020 16:12:55
	System	09 Dec 2020 16:12:55

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2020-12-19T10:37:50', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e7d7b38-4779-4d22-a503-9abb97bda7bf'	System	19 Dec 2020 17:38:32
User entered 'No (N)'	System	19 Dec 2020 17:38:32

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2020-12-19T10:38:07', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e7d7b38-4779-4d22-a503-9abb97bda7bf'	System	19 Dec 2020 17:38:32
User entered 'Yes (Y)'	System	19 Dec 2020 17:38:32

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-12-19T10:38:15', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e7d7b38-4779-4d22-a503-9abb97bda7bf'	System	19 Dec 2020 17:38:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 17:38:32

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2020-12-19T10:38:21', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e7d7b38-4779-4d22-a503-9abb97bda7bf' User entered '19 Dec 2020 10:38:21'	System	19 Dec 2020 17:38:32
	System	19 Dec 2020 17:38:32

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2020-12-23T14:55:20', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0a1b58b1-ba41-438e-b50e-f0dc7d1732df'	System	23 Dec 2020 21:55:52
User entered 'No (N)'	System	23 Dec 2020 21:55:52

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2020-12-23T14:55:39', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0a1b58b1-ba41-438e-b50e-f0dc7d1732df'	System	23 Dec 2020 21:55:52
User entered 'No (N)'	System	23 Dec 2020 21:55:52

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-12-23T14:55:48', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0a1b58b1-ba41-438e-b50e-f0dc7d1732df' User entered '23 Dec 2020 14:55:48'	System	23 Dec 2020 21:55:52
	System	23 Dec 2020 21:55:52

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2020-12-30T23:55:14', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2d167f65-5644-47a4-981e-07f04adc2bc9'	System	31 Dec 2020 06:55:27
User entered 'No (N)'	System	31 Dec 2020 06:55:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2020-12-30T23:55:19', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2d167f65-5644-47a4-981e-07f04adc2bc9'	System	31 Dec 2020 06:55:27
User entered 'No (N)'	System	31 Dec 2020 06:55:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2020-12-30T23:55:24', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2d167f65-5644-47a4-981e-07f04adc2bc9'	System	31 Dec 2020 06:55:27
User entered '30 Dec 2020 23:55:24'	System	31 Dec 2020 06:55:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcd399a)', Time: '2021-01-06T11:30:02', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '771df793-6e11-4fa0-b5ac-a1011bebd2cf'	System	06 Jan 2021 18:30:39
User entered 'No (N)'	System	06 Jan 2021 18:30:39

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2021-01-06T11:30:28', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '771df793-6e11-4fa0-b5ac-a1011bebd2cf'	System	06 Jan 2021 18:30:39
User entered 'No (N)'	System	06 Jan 2021 18:30:39

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-01-06T11:30:33', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '771df793-6e11-4fa0-b5ac-a1011bebd2cf' User entered '06 Jan 2021 11:30:33'	System	06 Jan 2021 18:30:39

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-01-14T22:10:11', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e521bb2-e5d4-4f1a-91d5-25753febbbea'	System	15 Jan 2021 05:11:12
User entered 'Yes (Y)'	System	15 Jan 2021 05:11:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2021-01-14T22:10:29', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e521bb2-e5d4-4f1a-91d5-25753febbbea'	System	15 Jan 2021 05:11:12
User entered 'No (N)'	System	15 Jan 2021 05:11:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcd399a)', Time: '2021-01-14T22:10:36', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e521bb2-e5d4-4f1a-91d5-25753febbbea'	System	15 Jan 2021 05:11:12
User entered 'No (N)'	System	15 Jan 2021 05:11:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 (92211691bcd399a)', Time: '2021-01-14T22:10:43', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e521bb2-e5d4-4f1a-91d5-25753febbbea'	System	15 Jan 2021 05:11:12
User entered 'Yes (Y)'	System	15 Jan 2021 05:11:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-01-14T22:10:56', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e521bb2-e5d4-4f1a-91d5-25753febbbea'	System	15 Jan 2021 05:11:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 05:11:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-01-14T22:11:01', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '7e521bb2-e5d4-4f1a-91d5-25753febbbea' User entered '14 Jan 2021 22:11:01'	System	15 Jan 2021 05:11:12
	System	15 Jan 2021 05:11:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcd399a)', Time: '2021-01-20T09:56:15', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '594e468a-d09a-4eff-bbf3-797ae05609cb'	System	20 Jan 2021 16:57:26
User entered 'Yes (Y)'	System	20 Jan 2021 16:57:26

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2021-01-20T09:56:21', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '594e468a-d09a-4eff-bbf3-797ae05609cb'	System	20 Jan 2021 16:57:26
User entered 'No (N)'	System	20 Jan 2021 16:57:26

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcd399a)', Time: '2021-01-20T09:56:28', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '594e468a-d09a-4eff-bbf3-797ae05609cb'	System	20 Jan 2021 16:57:26
User entered 'No (N)'	System	20 Jan 2021 16:57:26

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcd399a)', Time: '2021-01-20T09:57:03', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '594e468a-d09a-4eff-bbf3-797ae05609cb'	System	20 Jan 2021 16:57:26
User entered 'Yes (Y)'	System	20 Jan 2021 16:57:26

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2021-01-20T09:57:08', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '594e468a-d09a-4eff-bbf3-797ae05609cb'	System	20 Jan 2021 16:57:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Jan 2021 16:57:26

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2021-01-20T09:57:14', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '594e468a-d09a-4eff-bbf3-797ae05609cb' User entered '20 Jan 2021 09:57:14'	System	20 Jan 2021 16:57:26
	System	20 Jan 2021 16:57:26

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-01-28T13:33:27', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '72d74c1b-540b-49f3-b0ff-0499dfccf163'	System	28 Jan 2021 20:33:53
User entered 'No (N)'	System	28 Jan 2021 20:33:53

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2021-01-28T13:33:40', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '72d74c1b-540b-49f3-b0ff-0499dfccf163'	System	28 Jan 2021 20:33:53
User entered 'No (N)'	System	28 Jan 2021 20:33:53

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2021-01-28T13:33:49', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '72d74c1b-540b-49f3-b0ff-0499dfccf163'	System	28 Jan 2021 20:33:53
User entered '28 Jan 2021 13:33:49'	System	28 Jan 2021 20:33:53

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-02-03T10:14:08', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '051f5b20-eddb-4b96-b5bd-8a1d5961ccbc'	System	03 Feb 2021 17:14:41
User entered 'No (N)'	System	03 Feb 2021 17:14:41

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-02-03T10:14:17', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '051f5b20-eddb-4b96-b5bd-8a1d5961ccbc'	System	03 Feb 2021 17:14:41
User entered 'No (N)'	System	03 Feb 2021 17:14:41

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-02-03T10:14:22', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '051f5b20-eddb-4b96-b5bd-8a1d5961ccbc' User entered '03 Feb 2021 10:14:22'	System	03 Feb 2021 17:14:41
	System	03 Feb 2021 17:14:41

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

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 (92211691bcdf399a)', Time: '2021-02-17T15:38:37', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0b2e14ce-436b-4db8-a53e-34dafb9eee9c'	System	17 Feb 2021 22:40:27
User entered 'No (N)'	System	17 Feb 2021 22:40:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-02-17T15:40:11', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0b2e14ce-436b-4db8-a53e-34dafb9eee9c'	System	17 Feb 2021 22:40:27
User entered 'No (N)'	System	17 Feb 2021 22:40:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-02-17T15:40:24', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '0b2e14ce-436b-4db8-a53e-34dafb9eee9c'	System	17 Feb 2021 22:40:27
User entered '17 Feb 2021 15:40:24'	System	17 Feb 2021 22:40:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-02-24T14:50:45-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eee26b84-feb2-43d6-a887-1c80311c659b'	System	24 Feb 2021 21:56:23
User entered 'No (N)'	System	24 Feb 2021 21:56:23

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-02-24T14:50:51-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eee26b84-feb2-43d6-a887-1c80311c659b'	System	24 Feb 2021 21:56:23
User entered 'No (N)'	System	24 Feb 2021 21:56:23

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-02-24T14:50:56-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'eee26b84-feb2-43d6-a887-1c80311c659b' User entered '24 Feb 2021 14:50:56'	System	24 Feb 2021 21:56:23
	System	24 Feb 2021 21:56:23

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-03-03T01:52:53-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '89100bae-25da-4be1-a091-d7c3897f1842'	System	03 Mar 2021 08:53:11
User entered 'No (N)'	System	03 Mar 2021 08:53:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-03-03T01:52:59-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '89100bae-25da-4be1-a091-d7c3897f1842'	System	03 Mar 2021 08:53:11
User entered 'No (N)'	System	03 Mar 2021 08:53:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-03-03T01:53:05-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '89100bae-25da-4be1-a091-d7c3897f1842'	System	03 Mar 2021 08:53:11
User entered '03 Mar 2021 01:53:05'	System	03 Mar 2021 08:53:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcd399a)', Time: '2021-03-10T07:04:13-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b58863b3-bb42-4db0-b430-7d07ed32a107'	System	10 Mar 2021 14:05:08
User entered 'No (N)'	System	10 Mar 2021 14:05:08

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2021-03-10T07:04:20-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b58863b3-bb42-4db0-b430-7d07ed32a107'	System	10 Mar 2021 14:05:08
User entered 'No (N)'	System	10 Mar 2021 14:05:08

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-03-10T07:04:31-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'b58863b3-bb42-4db0-b430-7d07ed32a107'	System	10 Mar 2021 14:05:08
User entered '10 Mar 2021 07:04:31'	System	10 Mar 2021 14:05:08

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-03-24T09:00:04-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ce947463-e484-4931-a74d-f2833fe5f400'	System	24 Mar 2021 15:00:27
User entered 'No (N)'	System	24 Mar 2021 15:00:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcd399a)', Time: '2021-03-24T09:00:09-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ce947463-e484-4931-a74d-f2833fe5f400'	System	24 Mar 2021 15:00:27
User entered 'No (N)'	System	24 Mar 2021 15:00:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-03-24T09:00:17-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'ce947463-e484-4931-a74d-f2833fe5f400'	System	24 Mar 2021 15:00:27
User entered '24 Mar 2021 09:00:17'	System	24 Mar 2021 15:00:27

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcd399a)', Time: '2021-03-31T07:51:52-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'c4a75c1f-7cc5-4a6e-a740-fee89cfa373f'	System	31 Mar 2021 13:52:12
User entered 'No (N)'	System	31 Mar 2021 13:52:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-03-31T07:51:57-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'c4a75c1f-7cc5-4a6e-a740-fee89cfa373f'	System	31 Mar 2021 13:52:12
User entered 'No (N)'	System	31 Mar 2021 13:52:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-03-31T07:52:06-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'c4a75c1f-7cc5-4a6e-a740-fee89cfa373f' User entered '31 Mar 2021 07:52:06'	System	31 Mar 2021 13:52:12
	System	31 Mar 2021 13:52:12

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-04-07T11:53:17-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2feb4c23-b64d-4a40-9bda-96e538860075'	System	07 Apr 2021 17:53:45
User entered 'No (N)'	System	07 Apr 2021 17:53:45

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-04-07T11:53:29-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2feb4c23-b64d-4a40-9bda-96e538860075'	System	07 Apr 2021 17:53:45
User entered 'No (N)'	System	07 Apr 2021 17:53:45

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-04-07T11:53:39-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '2feb4c23-b64d-4a40-9bda-96e538860075'	System	07 Apr 2021 17:53:45
User entered '07 Apr 2021 11:53:39'	System	07 Apr 2021 17:53:45

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-04-14T11:46:21-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'd91a5ffa-d453-4506-8f7b-61aeb42f1d4b'	System	14 Apr 2021 17:52:11
User entered 'No (N)'	System	14 Apr 2021 17:52:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-04-14T11:52:01-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'd91a5ffa-d453-4506-8f7b-61aeb42f1d4b'	System	14 Apr 2021 17:52:11
User entered 'No (N)'	System	14 Apr 2021 17:52:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2021-04-14T11:52:06-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'd91a5ffa-d453-4506-8f7b-61aeb42f1d4b'	System	14 Apr 2021 17:52:11
User entered '14 Apr 2021 11:52:06'	System	14 Apr 2021 17:52:11

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-04-21T09:05:57-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '80acdca6-423e-49ba-bdd1-5a6c3e419362'	System	21 Apr 2021 15:06:15
User entered 'No (N)'	System	21 Apr 2021 15:06:15

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-04-21T09:06:03-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '80acdca6-423e-49ba-bdd1-5a6c3e419362'	System	21 Apr 2021 15:06:15
User entered 'No (N)'	System	21 Apr 2021 15:06:15

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-04-21T09:06:09-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '80acdca6-423e-49ba-bdd1-5a6c3e419362'	System	21 Apr 2021 15:06:15
User entered '21 Apr 2021 09:06:09'	System	21 Apr 2021 15:06:15

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[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 (92211691bcdf399a)', Time: '2021-04-28T01:33:05-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'c0e57f83-93cf-49d4-a060-7932bddefe1a' User entered 'No (N)'	System	29 Apr 2021 00:26:54
	System	29 Apr 2021 00:26:54

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

Have you been exposed to someone with 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 (92211691bcdf399a)', Time: '2021-04-28T01:33:11-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'c0e57f83-93cf-49d4-a060-7932bddefe1a'	System	29 Apr 2021 00:26:54
User entered 'No (N)'	System	29 Apr 2021 00:26:54

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcdf399a)', Time: '2021-04-28T01:33:19-06:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: 'c0e57f83-93cf-49d4-a060-7932bddefe1a'	System	29 Apr 2021 00:26:54
User entered '28 Apr 2021 01:33:19'	System	29 Apr 2021 00:26:54

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:05:30

US3892034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:21:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:05:30
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:05:30

US3892034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:21:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2021-03-03T01:52:15-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '793bda69-52cf-4d02-8f1b-388690efd060'	System	03 Mar 2021 08:52:32
User entered 'No (N)'	System	03 Mar 2021 08:52:32

US3892034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:21:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92211691bcd399a)', Time: '2021-03-03T01:52:28-07:00', User OID: 'PatientReportedOutcome (US3892034)', ODM File OID: '793bda69-52cf-4d02-8f1b-388690efd060' User entered '03 Mar 2021 01:52:28'	System	03 Mar 2021 08:52:32
	System	03 Mar 2021 08:52:32

US3892034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:59:45

US3892034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered '20 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:59:45

US3892034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:59:45

US3892034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:59:45

US3892034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User signature succeeded.	Michael Adams (b) (4)	09 Mar 2021 17:50:55
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	04 Dec 2020 14:59:49

US3892034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 10:09:14
User entered '1'	System	04 Dec 2020 14:59:49

US3892034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:12:15
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	28 Dec 2020 22:07:55

US3892034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:12:15
User entered '28 Dec 2020'	Courtney Jensen (b) (4)	28 Dec 2020 22:07:55

US3892034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:12:15
User entered 'Contact Made (CONTACT MADE)'	Courtney Jensen (b) (4) (b) (4)	28 Dec 2020 22:07:55

US3892034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:12:15
User entered empty.	Courtney Jensen (b) (4) (b) (4)	28 Dec 2020 22:07:55

US3892034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:12:50
User entered 'Yes (Y)'	Courtney Jensen (b) (4) (b) (4)	28 Dec 2020 22:08:00

US3892034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User entered '1'	System	28 Dec 2020 22:08:00

US3892034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 19:08:22

US3892034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	25 Jan 2021 19:08:33
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:08:33
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	25 Jan 2021 19:08:22
User entered '26 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:08:22

US3892034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:08:22

US3892034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:08:22

US3892034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:10:08

US3892034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User entered '1'	System	25 Jan 2021 19:10:08

US3892034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	22 Feb 2021 18:57:34

US3892034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered '22 Feb 2021'	Courtney Jensen (b) (4)	22 Feb 2021 18:57:34

US3892034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Courtney Jensen (b) (4)	22 Feb 2021 18:57:34

US3892034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:21:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	Courtney Jensen (b) (4)	22 Feb 2021 18:57:34

US3892034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	22 Feb 2021 18:57:54

US3892034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:40:48
User entered '1'	System	22 Feb 2021 18:57:54

US3892034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:17

US3892034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered '15 Mar 2021'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:17

US3892034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[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 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:17

US3892034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered 'VISIT4'	System	15 Mar 2021 17:46:17

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered empty.	System	30 Mar 2021 17:04:39

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55

US3892034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55

US3892034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:27

US3892034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered '15 Mar 2021'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:27

US3892034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:43

US3892034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered '15 Mar 2021'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:43

US3892034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered '11:14'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:43

US3892034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '15 Mar 2021 11:14'	System	15 Mar 2021 17:46:43

US3892034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	15 Mar 2021 17:46:48

US3892034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:21:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:20:55
User entered '1'	System	15 Mar 2021 17:46:48

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:21:56

[Date of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:39:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 18:39:45
User entered '23 Apr 2021' reason for change: Data Entry Error	Rachel Law (b) (4)	29 Apr 2021 18:39:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:12:55
User entered empty.	Rachel Law (b) (4)	29 Apr 2021 18:12:55
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:21:56

[Time of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:39:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 18:39:45
User entered '12:30' reason for change: Data Entry Error	Rachel Law (b) (4)	29 Apr 2021 18:39:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:12:55
User entered empty.	Rachel Law (b) (4)	29 Apr 2021 18:12:55
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:21:56

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Apr 2021 12:30'	System	29 Apr 2021 18:39:45
User entered empty.	System	29 Apr 2021 18:12:55

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:21:56

[Type of Contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:39:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 18:39:45
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Rachel Law (b) (4)	29 Apr 2021 18:39:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:12:55
User entered empty.	Rachel Law (b) (4)	29 Apr 2021 18:12:55
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:21:56

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:39:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 18:39:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Rachel Law (b) (4)	29 Apr 2021 18:39:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 18:12:55
User entered empty.	Rachel Law (b) (4)	29 Apr 2021 18:12:55
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Date of Visit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered '23 Apr 2021'	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered 'Yes (Y)'	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered 'No (N)'	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered '23 Apr 2021'	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Type of Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Rachel Law (b) (4)	29 Apr 2021 18:47:41

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered 'No (N)'	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[CLIA Certified?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	01 May 2021 21:11:21
	(b) (4)	
User entered empty.	Rachel Law (b) (4)	29 Apr 2021 18:47:41
	(b) (4)	

US3892034

Folder: Covid-19 Assessment 23 Apr 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:21:56

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 18:47:41

US3892034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	24 Apr 2021 03:37:14
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '23 Apr 2021'	Courtney Jensen (b) (4)	24 Apr 2021 03:37:14
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Home (Home)'	Courtney Jensen (b) (4)	24 Apr 2021 03:37:14
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	24 Apr 2021 03:37:14

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '23 Apr 2021'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '19:07'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Apr 2021 19:07'	System	24 Apr 2021 03:38:21

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered missing code ND - Not Done.	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	
DataPoint set to visible.	System	24 Apr 2021 03:37:14

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered missing code ND - Not Done.	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	
DataPoint set to visible.	System	24 Apr 2021 03:37:14

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '99.1' F	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Oral (Oral)'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '78'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Apr 2021 03:38:21

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '16'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Apr 2021 03:38:21

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '147'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Apr 2021 03:38:21

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '88'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:21
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:21:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Apr 2021 03:38:21

US3892034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:30
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:21:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '23 Apr 2021'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:30
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:21:56

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:40
	(b) (4)	

US3892034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:21:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '23 Apr 2021'	Courtney Jensen (b) (4)	24 Apr 2021 03:38:40
	(b) (4)	

US3892034

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	22 Jan 2021 01:03:58

US3892034

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '21 Jan 2021'	Andryelle Toledo (b) (4)	22 Jan 2021 01:03:58

US3892034

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[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 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:03:58

US3892034

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

Form: Visit Date

Generated On: 10 Jun 2021 10:21:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 01:03:58

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '21 Jan 2021'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[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 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	31 Mar 2021 22:09:39
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:05:49

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User closed query 'Kindly update EDC. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:44:20
Query 'Kindly update EDC. ' answered with 'Update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	31 Mar 2021 22:09:51
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andryelle Toledo (b) (4) (b) (4)	31 Mar 2021 22:09:39
User opened query 'Kindly update EDC. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 16:48:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:05:49

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '21 Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'mRNA-1273 (mRNA-1273)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'mRNA-1273 (mRNA-1273)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'mRNA-1273 (mRNA-1273)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'No (N)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User entered empty.	System	22 Jan 2021 01:04:30

US3892034

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

Form: Unblinding

Generated On: 10 Jun 2021 10:21:56

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User entered empty.	System	22 Jan 2021 01:04:30

US3892034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:55

US3892034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '21 Jan 2021'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:55

US3892034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '11:17'	Andryelle Toledo (b) (4)	22 Jan 2021 01:04:55

US3892034

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:21:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User entered '21 Jan 2021 11:17'	System	22 Jan 2021 01:04:55

US3892034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	22 Jan 2021 01:05:10

US3892034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '21 Jan 2021'	Andryelle Toledo (b) (4)	22 Jan 2021 01:05:10

US3892034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '11:29'	Andryelle Toledo (b) (4)	22 Jan 2021 01:05:10

US3892034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:21:56

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:44:52
User entered '21 Jan 2021 11:29'	System	22 Jan 2021 01:05:10

US3892034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:21:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:31
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day "138 and 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:31:48
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day "138 and 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SAE opened.' (Site from DM).	Andryelle Toledo (b) (4)	29 Mar 2021 18:18:15
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day "138 and 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:53:43
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:59:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Courtney Jensen (b) (4)	30 Dec 2020 22:51:50
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:52:48

US3892034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:33:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:33:53
Data point term sent to Coder	System	04 Feb 2021 17:32:44
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
User entered 'Right Lower quadrant pain' reason for change: New Information	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Foreign body in skin or subcutaneous tissue, LLT: Foreign body in skin or subcutaneous tissue - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:20:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:20:07
Data point term sent to Coder	System	15 Jan 2021 21:00:42
Coding entries removed.	Leslie Iverson (b) (4)	15 Jan 2021 21:00:04
User entered 'Foreign body R 3rd Finger' reason for change: New Information	Leslie Iverson (b) (4)	15 Jan 2021 21:00:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Splinter, LLT: Splinter - version MedDRA\23.0.	Coder Import (b) (4)	31 Dec 2020 13:06:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Dec 2020 13:06:33
Data point term sent to Coder	System	30 Dec 2020 22:56:53
User entered 'Metal splinter in middle finger on right hand.'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
	(b) (4)	
User entered 'No (N)'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
User entered '28 Dec 2020'	(b) (4)	
	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User entered empty.	System	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	15 Jan 2021 21:00:14
User entered 'No (N)' reason for change: Data Entry Error	System	15 Jan 2021 21:00:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Leslie Iverson (b) (4)	15 Jan 2021 21:00:14
User entered 'Yes (Y)'	(b) (4)	15 Jan 2021 21:00:04
	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '18 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:00:04
User entered empty.	(b) (4)	
	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User entered empty.	System	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

US3892034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Dec 2020 22:57:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Courtney Jensen (b) (4)	30 Dec 2020 22:57:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	30 Dec 2020 22:56:51
	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Dec 2020 22:57:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Dec 2020 22:57:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Courtney Jensen (b) (4)	30 Dec 2020 22:57:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Dec 2020 22:56:51
User entered empty.	System	30 Dec 2020 22:56:51
	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Dec 2020 22:57:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	30 Dec 2020 22:57:43
User opened query 'Data is required. Please complete.' (Site from System).	Courtney Jensen (b) (4)	30 Dec 2020 22:57:43
User entered empty.	(b) (4)	
	System	30 Dec 2020 22:56:51
	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	04 Feb 2021 17:32:35
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	04 Feb 2021 17:32:22
User entered '1' reason for change: New Information	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
User entered '0' reason for change: New Information	(b) (4)	15 Jan 2021 21:00:04
User entered '1'	Leslie Iverson (b) (4)	30 Dec 2020 22:56:51
	(b) (4)	
	Courtney Jensen (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Per DM CLR: Other Action Taken = Concomitant Procedure only, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:12:20
Query 'Per DM CLR: Other Action Taken = Concomitant Procedure only, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:30
User opened query 'Per DM CLR: Other Action Taken = Concomitant Procedure only, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 03:49:20
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0' reason for change: New Information	(b) (4)	04 Feb 2021 17:32:35
User entered '1' reason for change: New Information	Leslie Iverson (b) (4)	15 Jan 2021 21:00:04
User entered '0'	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:00:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:00:04
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 22:56:51
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:21:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'SUBJECT ATTRIBUTED TO ABDOMINAL EXERCISES. RESOLVED WITHOUT TREATMENT' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:53:25
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:32:22
User entered 'Foreign body removed and subject reports resolution.' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:00:04
User entered empty.	Courtney Jensen (b) (4)	30 Dec 2020 22:56:51

US3892034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User entered '0'	System	30 Dec 2020 22:56:51

US3892034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04
User entered '1'	System	04 Feb 2021 17:32:22
User entered '0'	System	30 Dec 2020 22:56:51

US3892034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:04

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:13:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:26:27
User entered		
'USA-US209-2021-mRNA-1273-P301000001'	System	19 Jan 2021 14:26:21
User entered 'New'	(b) (4), (b) (6)	19 Jan 2021 14:26:21

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:13:38
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Cerebral injuries NEC, PT: Craniocerebral injury, LLT: Traumatic brain injury - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 21:11:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 21:11:59
Data point term sent to Coder	System	15 Jan 2021 21:10:47
User entered 'Traumatic Brain Injury'	Leslie Iverson (b) (4)	15 Jan 2021 21:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:13:39
User entered 'Yes (Y)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:13:41
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:13:44
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:13:48
User entered '07 Jan 2021'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:13:52
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:13:54
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:00:49
User entered '08 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:10:27
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:13:59
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:14:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given.' (Site from DM). Query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given.' answered with 'No con. procedure or medication related ' (Site from DM). User opened query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Andryelle Toledo (b) (4) (b) (4) (b) (4), (b) (6)	05 Feb 2021 09:12:35 04 Feb 2021 18:03:51 30 Jan 2021 03:51:42
User entered 'Yes (Y)'	(b) (4), (b) (6) Leslie Iverson (b) (4) (b) (4)	21 Jan 2021 20:14:10 15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:14:12
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:14:14
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:14:19
User entered '1'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:48
User entered '07 Jan 2021'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:47
User entered '08 Jan 2021'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:45
User entered 'No (N)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:43
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:16:41
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:10:27
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:39
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:37
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:36
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:34
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:16:32
User entered 'Not Applicable (NOT APPLICABLE)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Per CDM: Please check Other action taken is marked as 'None' however related concomitant procedure is reported. Kindly reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 07:23:03
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:06:43
Query 'Per CDM: Please check Other action taken is marked as 'None' however related concomitant procedure is reported. Kindly reconcile the data and update as appropriate. Thank you.' answered with 'The medication reported is related with the others AE not with Traumatic Brain Injury' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	16 Feb 2021 17:38:24
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	16 Feb 2021 17:37:50
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	16 Feb 2021 17:37:04
User opened query 'Per CDM: Please check Other action taken is marked as 'None' however related concomitant procedure is reported. Kindly reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:38:31
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Feb 2021 18:01:53
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 18:01:53
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 18:01:53
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Feb 2021 17:35:59
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:30
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

US3892034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 18:06:46
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	16 Feb 2021 17:37:50
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	16 Feb 2021 17:37:04
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	16 Feb 2021 17:37:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:28
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:06:48
User closed query 'Per DM CLR: Treatment Required= Concomitant Procedure. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. Else, update this field. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:14:39
Query 'Per DM CLR: Treatment Required= Concomitant Procedure. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. Else, update this field. ' answered with 'No medical procedure related or con. medication' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 18:03:18
DataPoint Un-verified.	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 17:35:59
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 17:35:59
User opened query 'Per DM CLR: Treatment Required= Concomitant Procedure. Please review and confirm if there are any medical procedures performed for this AE other than the diagnostic procedure/s. If confirmed, please add these procedures in the Con Proc page as appropriate. Else, update this field. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 03:51:22
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:26
User entered '1'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Per source this was updated to Recovered/Resolved. Kindly update EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:54:03
Query 'Per source this was updated to Recovered/Resolved. Kindly update EDC.' answered with 'Per source this is completed with recovered/resolved with sequelae - Headache' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:10:48
User opened query 'Per source this was updated to Recovered/Resolved. Kindly update EDC.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 18:31:28
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:24
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:11:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:16:21
User entered 'Headache' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:11:43
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Kindly add anxiety, depression and prednisone allergy in the medical history section of CRF (noted from hospital discharge summary).' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:39:45
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Per DM CLR: Narrative = FELL ON ICE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 19:58:37
Query 'PV Query: Kindly add anxiety, depression and prednisone allergy in the medical history section of CRF (noted from hospital discharge summary).' answered with 'update' (Site from Safety).	Andryelle Toledo (b) (4)	25 Feb 2021 22:27:25
Query 'Per DM CLR: Narrative = FELL ON ICE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4)	25 Feb 2021 22:16:17
User opened query 'PV Query: Kindly add anxiety, depression and prednisone allergy in the medical history section of CRF (noted from hospital discharge summary).' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 20:03:58
User opened query 'Per DM CLR: Narrative = FELL ON ICE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:21:51
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:06:50
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:51:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Fax ER discharging summary today 12 Feb. 2021. Thank you' (Site from Safety).	Andryelle Toledo (b) (4)	12 Feb 2021 18:52:52
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:40:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:13:44
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Infection Disease: SARS-CoV-2 by PCR NEGATIVE. Collected on 07 Jan. 2021 at 13:13 MST.' (Site from Safety).	Andryelle Toledo (b) (4)	04 Feb 2021 18:01:02
DataPoint Un-verified.	Andryelle Toledo (b) (4)	04 Feb 2021 18:00:55
User entered 'SUBJECT FELL ON ICE AND LANDED ON HIS FACE. HE LOST CONSCIOUSNESS FOR 13 MINUTES AND WAS TRANSPORTED TO THE HOSPITAL. HE ALSO FRACTURED BOTH ORBITS AND ZYGOMATIC ARCHES AND NASAL BONE. HE REPORTS THAT THE CT BRAIN REVEALED SMALL HEMORRHAGE THAT RESOLVED BY THE NEXT DAY AND HE WAS DISCHARGED AFTER ONE OVERNIGHT. Infection Disease: SARS-CoV-2 by PCR NEGATIVE. Collected on 07 Jan. 2021 at 13:13 MST.' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:00:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:58:07
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:15:58
User entered 'Subject fell on ice and landed on his face. He lost consciousness for 13 minutes and was transported to the hospital. He also fractured both orbits and zygomatic arches and nasal bone. He reports that the CT brain revealed small hemorrhage that resolved by the next day and he was discharged after one overnight.'	Leslie Iverson (b) (4)	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 21:10:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Foreign body in skin or subcutaneous tissue, LLT: Foreign body in skin or subcutaneous tissue - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 15:56:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 15:56:39
Data point term sent to Coder	System	04 Feb 2021 17:47:09
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User entered 'Foreign body Right 3rd Finger' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Orbital fracture - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:35:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:35:08
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Orbital fracture - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:20:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:20:08
Data point term sent to Coder	System	15 Jan 2021 21:29:59
User entered 'FRACTURE ORBITS BILATERAL Non-displaced' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:29:08
Data point term sent to Coder	System	15 Jan 2021 21:19:50
User entered 'Fracture Orbits Bilateral'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User entered '07 Jan 2021'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User entered empty.	System	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 17:46:11
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User entered empty.	System	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Not Related (NOT RELATED)'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:19:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:19:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:19:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:19:18
User entered empty.	System	15 Jan 2021 21:19:18
	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18
	(b) (4)	

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '1'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:29:16
User entered '1'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Feb 2021 17:46:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Jan 2021 21:19:18
	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'FOREIGN BODY REMOVED AND SUBJECT REPORTS RESOLUTION.' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:46:11
User entered 'FRACTURE DID NOT PROLONG HOSPITALIZATION FOR TRAUMATIC BRAIN INJURY. Did not require surgery.' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:29:08
User entered 'Fracture did not prolong hospitalization for traumatic brain injury.'	Leslie Iverson (b) (4)	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User entered '0'	System	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12
User entered '1'	System	15 Jan 2021 21:19:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Orbital fracture - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:50:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:50:47
Data point term sent to Coder	System	04 Feb 2021 17:50:13
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 17:49:30
User entered 'FRACTURE ORBITS BILATERAL NON-DISPLACED' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:49:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Fractured zygoma - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:22:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 11:22:09
Data point term sent to Coder	System	15 Jan 2021 21:28:58
User entered 'FRACTURE ZYGOMATIC ARCHES BILATERAL Non-displaced' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:28:39
Data point term sent to Coder	System	15 Jan 2021 21:21:54
User entered 'Fracture Zygomatic Arches Bilateral'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

US3892034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '07 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

US3892034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	(b) (4) Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User entered empty.	System	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 22:15:42
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '25 Feb 2021' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 22:15:42
User entered empty.	Andryelle Toledo (b) (4)	25 Feb 2021 22:15:42
	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User entered empty.	System	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

US3892034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

US3892034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:21:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:21:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:21:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:20:57
User entered empty.	System	15 Jan 2021 21:20:57
	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:21:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:21:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:21:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:20:57
User entered empty.	System	15 Jan 2021 21:20:57
	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:49:30
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:28:01
User entered '0'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:49:30
User entered '0'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 21:28:01
User entered '1'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:15:42
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 22:51:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 22:51:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Rachel Law (b) (4) (b) (4)	11 Feb 2021 22:51:27
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Jan 2021 21:20:57
User entered empty.	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'FRACTURE DID NOT PROLONG HOSPITALIZATION FOR TRAUMATIC BRAIN INJURY. DID NOT REQUIRE SURGERY.' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:49:30
User entered 'FRACTURE DID NOT PROLONG HOSPITALIZATION FOR TRAUMATIC BRAIN INJURY. No surgery required.' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:28:39
User entered 'Fracture did not prolong hospitalization for traumatic brain injury.'	Leslie Iverson (b) (4)	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User entered '0'	System	15 Jan 2021 21:20:57

US3892034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17
User entered '1'	System	15 Jan 2021 21:20:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Fractured zygoma - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:52:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:52:04
Data point term sent to Coder	System	04 Feb 2021 17:51:18
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 17:51:09
User entered 'FRACTURE ZYGOMATIC ARCHES BILATERAL NON-DISPLACED' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:51:09
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Subarachnoid haemorrhage, LLT: Subarachnoid hemorrhage - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 18:44:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 18:44:05
Data point term sent to Coder	System	19 Jan 2021 21:46:55
Coding entries removed.	Leslie Iverson (b) (4)	19 Jan 2021 21:45:53
User entered 'Minimal subarachnoid HEMORRHAGE' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 21:45:53
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebral haemorrhage, LLT: Hemorrhage brain - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 10:36:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Jan 2021 10:36:07
Data point term sent to Coder	System	15 Jan 2021 21:22:54
User entered 'Brain hemorrhage'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '07 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User entered empty.	System	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:14:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:51:09
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '25 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:14:57
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:51:09
User entered '08 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User entered empty.	System	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4)	04 Feb 2021 17:51:09
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Leslie Iverson (b) (4)	19 Jan 2021 21:45:53
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:25:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:25:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:25:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:22:23
User entered empty.	System	15 Jan 2021 21:22:23
	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:25:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:25:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:25:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:22:23
User entered empty.	System	15 Jan 2021 21:22:23
	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:25:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:25:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:25:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:22:23
User entered empty.	System	15 Jan 2021 21:22:23
	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	25 Feb 2021 16:36:16
User entered '1' reason for change: Data Entry Error	System	25 Feb 2021 16:36:16
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Andryelle Toledo (b) (4)	25 Feb 2021 16:36:09
User entered '0' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 16:36:09
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Feb 2021 17:51:09
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	15 Jan 2021 21:27:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	15 Jan 2021 21:27:35
User entered '0'	System	15 Jan 2021 21:27:30
	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:50:21
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:36:22
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:36:09
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:22:20
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 17:51:09
User entered '0' reason for change: Data Entry Error	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:27:30
User entered '1'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:22:23

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:14:57
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 22:51:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 22:51:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Rachel Law (b) (4)	11 Feb 2021 22:51:47
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 17:51:09
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:51:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'FRACTURE DID NOT PROLONG HOSPITALIZATION FOR TRAUMATIC BRAIN INJURY. NO SURGERY REQUIRED.' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	04 Feb 2021 17:51:19
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:51:09
User entered 'Subject was hospitalized for TBI, the hemorrhage did not prolong hospitalization.'	Leslie Iverson (b) (4)	15 Jan 2021 21:22:23

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User entered '0'	System	15 Jan 2021 21:22:23

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21
User entered '1'	System	15 Jan 2021 21:22:23

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:21

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Subarachnoid haemorrhage, LLT: Subarachnoid hemorrhage - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:53:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:53:52
Data point term sent to Coder	System	04 Feb 2021 17:53:19
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 17:53:07
User entered 'MINIMAL SUBARACHNOID HEMORRHAGE' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:53:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 21:35:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 21:35:58
Data point term sent to Coder	System	15 Jan 2021 21:35:02
User entered 'Right lower quadrant pain'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 21:40:39
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '07 Oct 2020'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User entered empty.	System	15 Jan 2021 21:34:10

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:53:07
User entered '13 Oct 2020'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User entered empty.	System	15 Jan 2021 21:34:10

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)	(b) (4)	
reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:53:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:34:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:34:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:34:22
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:34:10
User entered empty.	System	15 Jan 2021 21:34:10
	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:34:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	15 Jan 2021 21:34:22
User opened query 'Data is required. Please complete.' (Site from System).	Leslie Iverson (b) (4)	15 Jan 2021 21:34:22
User entered empty.	(b) (4)	
	System	15 Jan 2021 21:34:10
	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:34:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 21:34:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:34:22
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 21:34:10
User entered empty.	System	15 Jan 2021 21:34:10
	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '1' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 16:36:54
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:53:07
User entered '1'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:48:25
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:36:59
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 16:36:54
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 01:22:30
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 17:53:07
User entered '0'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:34:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'SUBJECT WAS HOSPITALIZED FOR TBI, THE HEMORRHAGE DID NOT PROLONG HOSPITALIZATION.' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	04 Feb 2021 17:53:07
User entered 'SUBJECT ATTRIBUTED TO ABDOMINAL EXERCISES. RESOLVED WITHOUT Treatment' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:40:39
User entered 'Subject attributed to abdominal exercises. Resolved without medical attention.'	Leslie Iverson (b) (4)	15 Jan 2021 21:34:10

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User entered '0'	System	15 Jan 2021 21:34:10

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26
User entered '1'	System	15 Jan 2021 21:40:39
User entered '0'	System	15 Jan 2021 21:34:10

US3892034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:26

US3892034

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Subdural haematoma, LLT: Subdural hematoma - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 11:17:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 11:17:16
Data point term sent to Coder	System	19 Jan 2021 21:42:51
User entered 'Frontal Subdural Hematoma'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '07 Jan 2021'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User entered empty.	System	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '08 Jan 2021'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User entered empty.	System	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:42:39
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	19 Jan 2021 21:42:39
User opened query 'Data is required. Please complete.' (Site from System).	Leslie Iverson (b) (4)	19 Jan 2021 21:42:39
User entered empty.	(b) (4)	
	System	19 Jan 2021 21:42:23
	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:42:39
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	19 Jan 2021 21:42:39
User opened query 'Data is required. Please complete.' (Site from System).	Leslie Iverson (b) (4)	19 Jan 2021 21:42:39
User entered empty.	(b) (4)	
	System	19 Jan 2021 21:42:23
	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:42:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	19 Jan 2021 21:42:39
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:42:23
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '1'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:42:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 21:42:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Jan 2021 21:42:23
	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered "The hematoma did not prolong hospitalization and resolved on imaging the next day."	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User entered '0'	System	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34
User entered '1'	System	19 Jan 2021 21:42:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:34

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Maxillary antrum fracture - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 11:35:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 11:35:17
Data point term sent to Coder	System	19 Jan 2021 21:43:52
User entered 'Fracture left and right maxillary sinus'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '07 Jan 2021'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User entered empty.	System	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 22:12:48
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '25 Feb 2021' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 22:12:48
User entered empty.	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:48
	(b) (4)	
	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User entered empty.	System	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'No (N)'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:44:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	19 Jan 2021 21:44:00
User opened query 'Data is required. Please complete.' (Site from System).	Leslie Iverson (b) (4)	19 Jan 2021 21:44:00
User entered empty.	(b) (4)	
	System	19 Jan 2021 21:43:44
	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:44:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	19 Jan 2021 21:44:00
User opened query 'Data is required. Please complete.' (Site from System).	Leslie Iverson (b) (4)	19 Jan 2021 21:44:00
User entered empty.	(b) (4)	
	System	19 Jan 2021 21:43:44
	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 21:44:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 21:44:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 21:44:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 21:43:44
User entered empty.	System	19 Jan 2021 21:43:44
	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	19 Jan 2021 21:44:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Leslie Iverson (b) (4)	19 Jan 2021 21:44:04
User entered '0'	(b) (4)	
	System	19 Jan 2021 21:43:44
	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '0'	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Andryelle Toledo (b) (4)	25 Feb 2021 22:12:48
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 22:52:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 22:52:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Rachel Law (b) (4) (b) (4)	11 Feb 2021 22:52:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:43:44
User entered empty.	Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered empty.	Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered 'Fracture did not prolong hospitalization for TBI.'	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User entered '0'	System	19 Jan 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37
User entered '1'	System	19 Jan 2021 21:43:44

US3892034

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:37

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 09:17:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 09:17:11
Data point term sent to Coder	System	25 Feb 2021 22:12:42
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 22:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'Fall from on ice ground' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
Data point term sent to Coder	System	25 Feb 2021 22:10:40
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
Data point term sent to Coder	System	04 Feb 2021 17:55:22
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 17:54:34
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
Data point term sent to Coder	System	04 Feb 2021 17:34:54
User entered 'Right 3rd finger Foreign Body'	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered 'Yes (Y)'	(b) (4)	
	System	04 Feb 2021 17:54:34
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'No (N)' reason for change: Data Entry Error	System	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)'	System	04 Feb 2021 17:54:34
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'No (N)' reason for change: Data Entry Error	System	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)'	System	04 Feb 2021 17:54:34
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered '07 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '24 Dec 2020'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	
	System	04 Feb 2021 17:54:34
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
	(b) (4)	
User entered empty.	System	04 Feb 2021 17:34:43

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'No (N)' reason for change: Data Entry Error	System	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)'	System	04 Feb 2021 17:54:34
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User entered '07 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	(b) (4)	
	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
User entered '11 Jan 2021'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
	(b) (4)	
User entered empty.	System	04 Feb 2021 17:34:43

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	System	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'No (N)' reason for change: Data Entry Error	System	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)'	System	04 Feb 2021 17:54:34
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0'	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 22:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	(b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 17:54:34
User entered empty; reason for change Data Entry Error	System	04 Feb 2021 17:54:34
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 22:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	(b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 17:54:34
User entered empty; reason for change Data Entry Error	System	04 Feb 2021 17:54:34
User entered 'Not Related (NOT RELATED)'	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 22:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	(b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 17:54:34
User entered empty; reason for change Data Entry Error	System	04 Feb 2021 17:54:34
User entered 'Not Applicable (NOT APPLICABLE)'	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
User entered '0'	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
	(b) (4)	
	System	04 Feb 2021 17:54:34
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0' reason for change: Data Entry Error	(b) (4)	
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
User entered '1'	(b) (4)	
User entered '1'	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered '0' reason for change: Data Entry Error	(b) (4)	
User entered '0' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
User entered '1'	(b) (4)	
User entered '1'	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:21:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Feb 2021 22:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 22:12:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Feb 2021 22:12:08
DataPoint activated with code reason code Data required.	(b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Feb 2021 17:54:34
User entered empty; reason for change Data Entry Error	System	04 Feb 2021 17:54:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
	(b) (4)	04 Feb 2021 17:34:43

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:21:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty.	(b) (4)	04 Feb 2021 17:34:43

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:34
User entered 'FOREIGN BODY REMOVED AND SUBJECT REPORTS RESOLUTION.' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:53
	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:34:43
	(b) (4)	

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
	(b) (4)	
User entered '0'	System	04 Feb 2021 17:34:43

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52
	(b) (4)	
User entered '1'	System	04 Feb 2021 17:34:43

US3892034

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:21:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:46
DataPoint activated with code reason code Data required.	Andryelle Toledo (b) (4)	25 Feb 2021 22:10:40
DataPoint inactivated with code reason code Data not required.	Andryelle Toledo (b) (4)	04 Feb 2021 17:54:52

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:21:56

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:17:58
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:45:50

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PLANTAGO OVATA, PRODUCTSYNONYM: METAMUCIL [PLANTAGO OVATA] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 20:53:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:53:55
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PLANTAGO OVATA, PRODUCTSYNONYM: METAMUCIL [PLANTAGO OVATA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:52:48
Data point term sent to Coder	System	03 Sep 2020 20:52:45
User closed query 'CDM oding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	03 Sep 2020 20:51:57
Query 'CDM oding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'The correct name is Metamucil. Data fixed.' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 20:51:57
Data point term sent to Coder	System	03 Sep 2020 20:51:44
User entered 'METAMUCiL' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	03 Sep 2020 20:50:51

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM oding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	03 Sep 2020 08:04:32
Data point term sent to Coder	System	02 Sep 2020 19:47:21
User entered 'METAMUCOL'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User closed query 'Per DM CLR: Please note that this condition not expected to be given as a prophylaxis and not recorded on the MH eCRF. Please review Con Med use, remove the term 'Supplement' and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). Query 'Per DM CLR: Please note that this condition not expected to be given as a prophylaxis and not recorded on the MH eCRF. Please review Con Med use, remove the term 'Supplement' and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'The indication is supplement per PA. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:06:20
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:51:23
User opened query 'Per DM CLR: Please note that this condition not expected to be given as a prophylaxis and not recorded on the MH eCRF. Please review Con Med use, remove the term 'Supplement' and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 03:15:07
User entered 'Yes (Y)'	Andryelle Toledo (b) (4) (b) (4)	02 Sep 2020 19:47:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:06:23
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'The indication is supplement per PA. ' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 19:51:26
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 03:14:38
User entered 'SUPPLEMENT'	Andryelle Toledo (b) (4) (b) (4)	02 Sep 2020 19:47:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '1'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'TSP'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'twice daily (BID)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'UN May 2020'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:47:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 19:47:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 19:47:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 19:47:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 19:50:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 19:50:15
Data point term sent to Coder	System	02 Sep 2020 19:49:24
User entered 'FLOMAX'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Benign prostatic hyperplasia'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '0.4'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'UN Aug 2019'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Sep 2020 19:48:29
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 19:48:29

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 19:48:29

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 19:48:29

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
	(b) (4)	
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 10:01:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 10:01:52
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 18:06:50
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered 'lidocaine' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
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)	17 Jan 2021 12:05:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Jan 2021 12:05:09
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 21:03:43
User entered 'Amoxicillin'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Foreign body Right 3rd finger' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered 'Fracture orbit bilateral'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered '875'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'cc' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'once (ONCE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered 'twice daily (BID)'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
Data Entry Error	(b) (4)	
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Intradermal' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '11 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered '07 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '11 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:05:59
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:03:28
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User entered empty.	System	04 Feb 2021 18:05:59
User entered '2'	System	15 Jan 2021 21:03:28

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User entered empty.	System	04 Feb 2021 18:05:59
User entered '1'	System	15 Jan 2021 21:03:28

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:55
User entered empty.	System	04 Feb 2021 18:05:59
User entered '804 (804)'	System	15 Jan 2021 21:03:28

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
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)	04 Feb 2021 18:08:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 18:08:53
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 18:07:52
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 18:07:23
	(b) (4)	
User entered 'Amoxicillin' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:07:23
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Jan 2021 12:14:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Jan 2021 12:14:08
	(b) (4)	
Data point term sent to Coder	System	15 Jan 2021 21:04:44
User entered 'Celebrex'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Fracture Orbit bilateral'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '875' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:07:23
	(b) (4)	
User entered '200'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Andryelle Toledo (b) (4)	04 Feb 2021 18:07:23
Data Entry Error	(b) (4)	
User entered 'as needed (PRN)'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '08 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:07:23
	(b) (4)	
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '17 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:07:23
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:04:13
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User entered '2'	System	04 Feb 2021 18:07:23
User entered empty.	System	15 Jan 2021 21:04:13

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User entered '1'	System	04 Feb 2021 18:07:23
User entered empty.	System	15 Jan 2021 21:04:13

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:59
User entered '804 (804)'	System	04 Feb 2021 18:07:23
User entered empty.	System	15 Jan 2021 21:04:13

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 18:11:04
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Feb 2021 18:11:04
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	04 Feb 2021 18:10:05
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
Coding entries removed.	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
User entered 'Celebrex' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Jan 2021 13:12:10
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Jan 2021 13:12:10
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	15 Jan 2021 21:05:45
User entered 'Lidocaine'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'FRACTURE ORBIT BILATERAL'	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
reason for change: Data Entry Error	(b) (4)	
User entered 'Foreign Body R 3rd Finger'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 20:16:50
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	24 Feb 2021 17:38:00
	(b) (4)	
User entered '200' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	24 Feb 2021 17:37:53
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 08:46:44
User entered '280' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
User entered '1'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
User entered 'mL (mL)'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '08 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
User entered '11 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '0'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered '17 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:10:03
	(b) (4)	
User entered '11 Jan 2021'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
	(b) (4)	
User entered 'No (N)'	Leslie Iverson (b) (4)	15 Jan 2021 21:05:23
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User entered empty.	System	04 Feb 2021 18:10:03
User entered '1'	System	15 Jan 2021 21:05:23

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User entered empty.	System	04 Feb 2021 18:10:03
User entered '1'	System	15 Jan 2021 21:05:23

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:03
User entered empty.	System	04 Feb 2021 18:10:03
User entered '804 (804)'	System	15 Jan 2021 21:05:23

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 03:43:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 03:43:27
Data point term sent to Coder	System	24 Apr 2021 03:42:01
User entered 'Robitussin DM'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'No (N)'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Upper Respiratory Infection'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '20'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'mL (mL)'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'as needed (PRN)'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Oral (ORAL)'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '23 Apr 2021'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered '0'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:39:59
	(b) (4)	
User entered 'No (N)'	Courtney Jensen (b) (4)	24 Apr 2021 03:41:06
	(b) (4)	

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 03:41:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 03:41:06

US3892034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:21:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Apr 2021 03:41:06

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:21:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:31
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 17:02:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:02:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	15 Jan 2021 21:00:33
User entered 'No (N)'	Andryelle Toledo (b) (4)	03 Sep 2020 20:50:16

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:28:20
User entered '07 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 18:12:06
User entered '11 Jan 2021'	Leslie Iverson (b) (4) (b) (4)	15 Jan 2021 21:00:56

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 20:55:24
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please confirm and update recorded data to reflect a procedure/surgery or non-drug therapy. Otherwise, delete if necessary or provide clarification.	(b) (4), (b) (6)	01 Mar 2021 17:22:44
' (Site from DM).		
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please confirm and update recorded data to reflect a procedure/surgery or non-drug therapy. Otherwise, delete if necessary or provide clarification.	Andryelle Toledo (b) (4)	26 Feb 2021 14:19:23
' answered with 'Udpate' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	26 Feb 2021 14:19:18
	(b) (4)	
User entered 'CT Brain/ Head' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	26 Feb 2021 14:19:18
	(b) (4)	
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please confirm and update recorded data to reflect a procedure/surgery or non-drug therapy. Otherwise, delete if necessary or provide clarification.	(b) (4), (b) (6)	26 Feb 2021 11:31:25
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:28:22
User entered 'Traumatic Brain Injury' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:12:06
	(b) (4)	
User entered 'Removal foreign body R 3rd finger'	Leslie Iverson (b) (4)	15 Jan 2021 21:00:56
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 20:55:27
DataPoint Un-verified.		
	Andryelle Toledo (b) (4)	26 Feb 2021 14:19:18
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason	Andryelle Toledo (b) (4)	26 Feb 2021 14:19:18
for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:28:25
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	15 Jan 2021 21:00:56
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:21:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 18:28:27
User entered empty.	Leslie Iverson (b) (4)	15 Jan 2021 21:00:56
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:15
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 18:17:19
User entered '07 Jan 2021'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:37:00
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:15
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Removal Foreign Body Right 3Rd finger' reason for change: Data Entry Error	(b) (4)	
User entered 'CT Scan Head'	Andryelle Toledo (b) (4)	04 Feb 2021 18:17:19
	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:37:00
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:15
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	15 Jan 2021 21:37:00

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:21:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:15
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered empty.	(b) (4) Leslie Iverson (b) (4)	15 Jan 2021 21:37:00

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '07 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 18:19:22
User entered '08 Jan 2021'	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:37:22
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'CT MAXILLOFACIAL' reason for change: Data Entry Error	(b) (4)	
User entered 'CT Scan Head'	Andryelle Toledo (b) (4)	04 Feb 2021 18:19:22
	(b) (4)	
	Leslie Iverson (b) (4)	15 Jan 2021 21:37:22
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Adverse Event (AE)'	Leslie Iverson (b) (4)	15 Jan 2021 21:37:22

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:21:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered empty.	(b) (4) Leslie Iverson (b) (4)	15 Jan 2021 21:37:22

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:26
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '07 Jan 2021'	Leslie Iverson (b) (4)	19 Jan 2021 21:46:45

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:26
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Chest X-Ray' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Feb 2021 18:19:58
User entered 'CT maxillofacial'	(b) (4)	
	Leslie Iverson (b) (4)	19 Jan 2021 21:46:45
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:26
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
User entered 'Adverse Event (AE)'	Andryelle Toledo (b) (4)	04 Feb 2021 18:20:57
	(b) (4)	
	Leslie Iverson (b) (4)	19 Jan 2021 21:46:45
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:21:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:26
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:46:45

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:21:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:32
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	(b) (4)	19 Jan 2021 21:47:09
User entered '07 Jan 2021' reason for change: Data Entry Error	Leslie Iverson (b) (4)	19 Jan 2021 21:47:09
User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	(b) (4)	19 Jan 2021 21:47:02
User entered '07 Jan 2020'	System	19 Jan 2021 21:47:02
	Leslie Iverson (b) (4)	19 Jan 2021 21:47:02
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:32
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Pelvis X-Ray' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 18:20:40
User entered 'Chest X-ray'	Leslie Iverson (b) (4)	19 Jan 2021 21:47:02
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:32
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Diagnostic (DIAGNOSTIC)'	Leslie Iverson (b) (4)	19 Jan 2021 21:47:02

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:21:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:32
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:47:02

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:55:42
User entered '08 Jan 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:21:36
User entered '07 Jan 2021'	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:47:29

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:55:45
User entered 'CT Brain/Head' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Feb 2021 18:21:36
User entered 'Pelvis X-ray'	Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 21:47:29

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:55:46
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Feb 2021 18:21:36
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:47:29
	(b) (4)	

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:21:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:55:49
User entered empty.	Leslie Iverson (b) (4) (b) (4)	19 Jan 2021 21:47:29

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:44
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered '07 Jan 2021'	Leslie Iverson (b) (4)	19 Jan 2021 21:48:15

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:44
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'CT scan Spine/Cervical'	Leslie Iverson (b) (4)	19 Jan 2021 21:48:15

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:44
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered 'Adverse Event (AE)'	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:48:15

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:21:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:44
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
User entered empty.	(b) (4) Leslie Iverson (b) (4)	19 Jan 2021 21:48:15

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:55:58
User entered '25 Feb 2021'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:18:11

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:21:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:56:00
User entered 'CT Brain/Head'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:18:11

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:21:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:56:02
User entered 'Diagnostic (DIAGNOSTIC)'	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:18:11

US3892034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 10:21:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:28:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:56:04
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	25 Feb 2021 22:18:11

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered		
'USA-US209-2021-MRNA-1273-P301000001'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Michael'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Adams'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '5251 S Green St'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Murray'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'UT'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '84123'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:13:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:59:38
User entered 'US'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Feb 2021 16:00:00
User entered '3'	System	16 Feb 2021 18:52:36
User entered '2'	System	05 Feb 2021 16:14:19
User entered '1'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered		
'USA-US209-2021-MRNA-1273-P301000001'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Michael'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Adams'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '5251 S Green St'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Murray'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'UT'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '84123'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:13:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:59:38
User entered 'US'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Feb 2021 16:00:00
User entered '3'	System	16 Feb 2021 18:52:36
User entered '2'	System	05 Feb 2021 16:14:19
User entered '1'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
User entered '19/Jan/2021 14:27'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 16:13:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:59:38
User entered '1'	(b) (4), (b) (6)	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered		
'USA-US209-2021-MRNA-1273-P301000001'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Michael'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Adams'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '5251 S Green St'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Murray'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'UT'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '84123'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 16:13:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:59:38
User entered 'US'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Feb 2021 16:00:00
User entered '3'	System	16 Feb 2021 18:52:36
User entered '2'	System	05 Feb 2021 16:14:19
User entered '1'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:01:56
User entered '05/Feb/2021 11:14'	System	05 Feb 2021 16:14:19

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 18:01:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:52:53
User entered '1'	(b) (4), (b) (6)	05 Feb 2021 16:14:19

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered		
'USA-US209-2021-MRNA-1273-P301000001'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Michael'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Adams'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '5251 S Green St'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Murray'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'UT'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '84123'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Feb 2021 16:13:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:59:38
User entered 'US'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Feb 2021 16:00:00
User entered '3'	System	16 Feb 2021 18:52:36
User entered '2'	System	05 Feb 2021 16:14:19
User entered '1'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:01:56
User entered '16/Feb/2021 13:52'	System	16 Feb 2021 18:52:36

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 18:01:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 18:52:53
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 18:52:36

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered		
'USA-US209-2021-MRNA-1273-P301000001'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Yes (Y)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'No (N)'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Michael'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Adams'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '5251 S Green St'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'Murray'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered 'UT'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:59:38
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:27:50
User entered '84123'	System	19 Jan 2021 14:26:21

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 16:13:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:59:38
User entered 'US'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 10:21:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	26 Feb 2021 16:00:00
User entered '3'	System	16 Feb 2021 18:52:36
User entered '2'	System	05 Feb 2021 16:14:19
User entered '1'	System	19 Jan 2021 14:27:58

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:21:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:01:11
User entered '26/Feb/2021 10:59'	System	26 Feb 2021 16:00:00

US3892034

Folder: SAE USA-US209-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:21:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:25:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 19:01:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:00:06
User entered '1'	(b) (4), (b) (6)	26 Feb 2021 16:00:00