

US3592226 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:20:38

All time stamps listed in this document are displayed in GMT

US3592226

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 09:35:48

Generated On: 10 Jun 2021 08:20:38

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:30:08

Generated On: 10 Jun 2021 08:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 16:30:08

Generated On: 10 Jun 2021 08:20:38

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 16:30:08

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Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 16:30:08

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 16:30:08

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 16:30:08

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Condition	ALLERGY TO CECLOR
Start date (dd MMM yyyy)	UN (b) (6) 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 16:30:08

Generated On: 10 Jun 2021 08:20:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 16:30:08

Generated On: 10 Jun 2021 08:20:38

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 16:30:08

Generated On: 10 Jun 2021 08:20:38

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:30:08

Generated On: 10 Jun 2021 08:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 15:45
Height (xxx.x)	173.0 cm
Weight (xxx.x)	81.2 kg
BMI (xxx.x)	27.13088 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:30:08

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 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) 05 Mar 2021 16:30:08

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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) 05 Mar 2021 16:30:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:00:19

Generated On: 10 Jun 2021 08:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 16:00:19

Generated On: 10 Jun 2021 08:20:38

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 105262

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) 05 Mar 2021 16:00:21

Generated On: 10 Jun 2021 08:20:38

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) 05 Mar 2021 16:00:21

Generated On: 10 Jun 2021 08:20:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:00:21

Generated On: 10 Jun 2021 08:20:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	17:33 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 17:33
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:00:19

Generated On: 10 Jun 2021 08:20:38

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) 05 Mar 2021 16:00:18

Generated On: 10 Jun 2021 08:20:38

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 17:02 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 17:02

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) 05 Mar 2021 16:00:19

Generated On: 10 Jun 2021 08:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 AUG 2020
Collection time (00:00-23:59)	16:25 (24 HR)
Collection date and time (derived)	18 AUG 2020 16:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:00:17

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:17	18 AUG 2020 16:17
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:18

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

18 AUG 2020 17:40

PC Open Date & Time

18 AUG 2020 17:22

PC Close Date & Time

18 AUG 2020 19:52

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

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

18 AUG 2020 20:47

PC Close Date & Time

19 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

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

19 AUG 2020 14:04

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

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

20 AUG 2020 17:07

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 15:58

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

22 AUG 2020 15:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

96.6 °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

23 AUG 2020 15:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 15:39

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 17:41

PC Open Date & Time

18 AUG 2020 17:22

PC Close Date & Time

18 AUG 2020 19:52

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 ☐

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.**

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

PC Open Date & Time

18 AUG 2020 20:47

PC Close Date & Time

19 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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

19 AUG 2020 14:04

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

20 AUG 2020 17:07

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	21 AUG 2020 15:58
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

22 AUG 2020 15:15

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

23 AUG 2020 15:39

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

24 AUG 2020 15:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 17:41
PC Open Date & Time	18 AUG 2020 17:22
PC Close Date & Time	18 AUG 2020 19:52

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 AUG 2020 20:47

PC Close Date & Time

19 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

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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US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 14:05
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

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)

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:07
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

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)

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 15:58
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

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EAB) (1725)

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 15:15
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

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)

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 15:39
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

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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US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 15:40
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3592226

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:00:22

Generated On: 10 Jun 2021 08:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:00:23

Generated On: 10 Jun 2021 08:20:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	16:24 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 16:24
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:00:23

Generated On: 10 Jun 2021 08:20:38

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	17:42 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 17:42
Temperature (xxx.x)	100.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3592226

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:00:22

Generated On: 10 Jun 2021 08:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:00:22

Generated On: 10 Jun 2021 08:20:38

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 17:09 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 17:09

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

US3592226

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:00:22

Generated On: 10 Jun 2021 08:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 SEP 2020
Collection time (00:00-23:59)	16:47 (24 HR)
Collection date and time (derived)	15 SEP 2020 16:47

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:00:22

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:29	15 SEP 2020 16:29
Nasopharyngeal Swab 2	No		

US3592226

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:22

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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

100.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:39

PC Open Date & Time

15 SEP 2020 17:29

PC Close Date & Time

15 SEP 2020 19:59

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

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

15 SEP 2020 20:54

PC Close Date & Time

16 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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

16 SEP 2020 16:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

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

17 SEP 2020 15:35

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

97.3 °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

18 SEP 2020 12:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

19 SEP 2020 15:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

97.6 °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

20 SEP 2020 17:53

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

21 SEP 2020 17:29

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 17:39

PC Open Date & Time

15 SEP 2020 17:29

PC Close Date & Time

15 SEP 2020 19:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 ☐

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.**

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

PC Open Date & Time

15 SEP 2020 20:54

PC Close Date & Time

16 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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

16 SEP 2020 16:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

17 SEP 2020 15:35

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

18 SEP 2020 12:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

19 SEP 2020 15:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

20 SEP 2020 17:53

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

21 SEP 2020 17:29

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 17:40
PC Open Date & Time	15 SEP 2020 17:29
PC Close Date & Time	15 SEP 2020 19:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 20:54

PC Close Date & Time

16 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

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)

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 16:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

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EAB) (1725)

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 15:36
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

EAB) (1725)

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US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

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EAB) (1725)

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 15:41
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

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)

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 17:53
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

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EAB) (1725)

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 17:29
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3592226

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:29:45

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:00:16

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:16

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:00:17

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:16

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:00:24

Generated On: 10 Jun 2021 08:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:00:24

Generated On: 10 Jun 2021 08:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	16:19 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 16:19
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592226

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:00:23

Generated On: 10 Jun 2021 08:20:38

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.

US3592226

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:00:23

Generated On: 10 Jun 2021 08:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	16:34 (24 HR)
Collection date and time (derived)	15 OCT 2020 16:34

US3592226

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:23

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 OCT 2020 07:16:23
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

26 OCT 2020 21:02:45

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 11:06:34
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 14:54:31
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 12:10:16
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

30 NOV 2020 19:55:23

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 04:44:37
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

10 DEC 2020 08:06:10

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

19 DEC 2020 18:45:57

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

24 DEC 2020 21:25:47

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 JAN 2021 06:47:07
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 11:37:29

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

18 JAN 2021 20:50:45

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

21 JAN 2021 11:07:28

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

Date and time of submission

29 JAN 2021 18:45:14

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

05 FEB 2021 20:34:58

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

13 FEB 2021 21:43:31

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 00:01:37
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 12:01:35
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

Date and time of submission

04 MAR 2021 00:41:31

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

12 MAR 2021 13:50:25

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

19 MAR 2021 08:40:50

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

25 MAR 2021 20:46:58

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 17:07:23
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 09:53:37
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

18 APR 2021 18:15:05

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 17:03:55

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

Date and time of submission

29 APR 2021 00:39:29

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3592226

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:20:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:01:46

US3592226

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:54:59

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:54:59

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592226

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

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

Visit date (dd MMM yyyy)	4 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 13:19
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592226

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 MAR 2021

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

US3592226

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	13:49 (24 HR)
Collection date and time (derived)	4 MAR 2021 13:49

US3592226

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592226

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592226

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:20:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3592226

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:35:48

Generated On: 10 Jun 2021 08:20:38

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

Visit date (dd MMM yyyy)	4 MAR 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
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US3592226

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 09:35:48

Generated On: 10 Jun 2021 08:20:38

Date of updated informed consent (dd MMM yyyy) 4 MAR 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) 4 MAR 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 _____

US3592226

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:35:48

Generated On: 10 Jun 2021 08:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	13:49 (24 HR)
Collection date and time (derived)	4 MAR 2021 13:49

US3592226

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 09:35:48

Generated On: 10 Jun 2021 08:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00 - 23:59)	13:35
Collection Date and Time (derived)	4 MAR 2021 13:35

US3592226

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:55:37

Generated On: 10 Jun 2021 08:20:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

AEID	
Adverse event	SORE THROAT
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

AEID	USA-US103-2021-MRNA-1273-P30 1000001
Adverse event	SPINAL CORD ABSCESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

SUBJECT REPORTS HE WAS
HAVING BACK PAIN ON
17DEC2020 AND WENT TO THE
EMERGENCY ROOM. WAS
FOUND TO HAVE AN ABSCESS
ON HIS SPINAL CORD THAT
REQUIRED EMERGENCY
SURGERY DUE TO THE
LIKELIHOOD OF IT
INFILTRATING THE SPINAL
FLUID. IS CURRENTLY STILL IN
THE HOSPITAL BEING
TREATED WITH VANCOMYCIN
FOR POST-SURGICAL
INFECTION. RELEASE OF
RECORDS HAS BEEN SENT.

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

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 15:55:37

Generated On: 10 Jun 2021 08:20:38

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

Yes ☒

No ☐

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

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:49:08

Generated On: 10 Jun 2021 08:20:38

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:49:08

Generated On: 10 Jun 2021 08:20:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3592226

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 May 2021 19:54:33

Generated On: 10 Jun 2021 08:20:38

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3592226

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:20:38

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

US3592226

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:38

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 ☐

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

SAEID	USA-US103-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

SAEID	USA-US103-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	15/JAN/2021 07:10
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

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 09:35:49

Generated On: 10 Jun 2021 08:20:38

SAEID	USA-US103-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/APR/2021 06:06
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

US3592226 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592226

Form: Participant Creation

Generated On: 10 Jun 2021 08:20:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:20:57
User entered 'US3592226'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 20:54:20

US3592226

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 22:06:13

US3592226

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:25
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 20:54:21

US3592226

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Aug 2020 22:06:13

US3592226

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'SCRN'	System	18 Aug 2020 22:06:13

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered (b) (6) 1986'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 20:54:22

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '34'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'YEARS'	System	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '34'	System	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered 'Male (M)'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered 'l'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 22:06:30

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:59
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'Aug 2020'	System	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '2020'	System	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:59
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:59
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:59
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:59
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 22:06:40

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:21:59
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 20:54:21

US3592226

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'l'	System	18 Aug 2020 22:06:44

US3592226

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:23:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 22:06:44

US3592226

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:20:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:23:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:52:12

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
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: Allergy to antibiotic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:54:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 20:54:05
Data point term sent to Coder	System	19 Aug 2020 20:53:21
User entered 'allergy to ceclor'	(b) (4), (b) (6)	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'un (b) (6) 1986'	(b) (4), (b) (6)	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered (b) (6) 1986'	System	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '1986'	System	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered empty.	System	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered empty.	System	19 Aug 2020 20:52:52

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 21:40:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 21:40:59
Data point term sent to Coder	System	12 Jan 2021 21:24:26
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:24:25
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	06 Oct 2020 09:04:14
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	30 Sep 2020 21:18:08
' answered with 'No medication taken for hypertension ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	28 Sep 2020 09:51:33
' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 20:55:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 20:55:07

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Aug 2020 20:54:23
User entered 'hypertension'	(b) (4), (b) (6)	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'un UNK 2009'	(b) (4), (b) (6)	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'Jan 2009'	System	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '2009'	System	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered empty.	System	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered empty.	System	19 Aug 2020 20:54:15

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Jan 2021 21:25:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 21:25:05
Data point term sent to Coder	System	12 Jan 2021 21:24:28
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:24:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 20:56:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 20:56:05
Data point term sent to Coder	System	19 Aug 2020 20:55:25
User entered 'chronic back pain'	(b) (4), (b) (6)	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'Jan 2010'	System	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '2010'	System	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered empty.	System	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered empty.	System	19 Aug 2020 20:55:06

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 21:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Jan 2021 21:25:04
Data point term sent to Coder	System	12 Jan 2021 21:24:26
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:24:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 21:04:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 21:04:09
Data point term sent to Coder	System	19 Aug 2020 21:03:40
User entered 'vasectomy'	(b) (4), (b) (6)	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'un UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 06:20:36
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 19:28:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 19:28:50
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:52:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered 'un UNK 2012' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 19:28:50
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:24:25
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'Jan 2012'	System	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '2012'	System	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'Jan 2012'	System	30 Sep 2020 19:28:50
User entered empty.	System	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '2012'	System	30 Sep 2020 19:28:50
User entered empty.	System	19 Aug 2020 21:02:40

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered '15:45'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered '18 Aug 2020 15:45'	System	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered '173.0' cm	(b) (4), (b) (6)	19 Aug 2020 21:04:53
DataPoint set to visible.	System	18 Aug 2020 22:06:44

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered '81.2' kg	(b) (4), (b) (6)	19 Aug 2020 21:04:53
DataPoint set to visible.	System	18 Aug 2020 22:06:44

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
Amendment Manager: User entered '27.13088'	System	17 Sep 2020 00:13:05
User entered '27.1'	System	19 Aug 2020 21:04:53
DataPoint set to visible.	System	18 Aug 2020 22:06:44

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'kg/m2'	System	19 Aug 2020 21:04:53
DataPoint set to visible.	System	18 Aug 2020 22:06:44

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 11:30:56
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'removed VS per CCGs' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 19:41:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:41:28
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 06:52:18
User entered '98.3' F	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:41:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:41:28
User entered '87'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'bpm'	System	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:41:28
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'breaths/min'	System	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:41:28
User entered '118'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'mmHg'	System	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:41:28
User entered '84'	(b) (4), (b) (6)	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User entered 'mmHg'	System	19 Aug 2020 21:04:53

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44

US3592226

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44

US3592226

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:42:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:53:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:05:14

US3592226

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:17
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:40:38
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:40:38
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 20:40:38
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:40:24
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:40:24
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	17 Sep 2020 20:40:24
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Sep 2020 20:40:24
User entered '15 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 20:40:24
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 20:42:12
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:42:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:53:10
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:05:14

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:06:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:07:03
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
User entered 'l'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:44
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:25:34
User entered 'goes grocery shopping a few times a week'	(b) (4), (b) (6)	19 Aug 2020 21:06:40

US3592226

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:51:41

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:12
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 20:51:41

US3592226

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[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 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 20:51:41

US3592226

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'VISIT1'	System	19 Aug 2020 20:51:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 21:39:22

US3592226

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:26:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:26:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 21:39:22
User entered '105262' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 21:39:22

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 21:39:22

US3592226

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

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 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:07:52

US3592226

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

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 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:07:52

US3592226

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:07:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:07:52

US3592226

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:07:52

US3592226

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:26:22
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:33:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:24:52

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:53:57
User entered '173.0' cm	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:53:57
User entered '81.2' kg	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:53:57
User entered '173.0' cm	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:53:57
User entered '81.2' kg	(b) (4), (b) (6)	19 Aug 2020 21:11:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:36:26
User closed query 'Please confirm Time of Assessment inconsistent with source whereas source reflects time to be 16:07.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 16:36:24
Query 'Please confirm Time of Assessment inconsistent with source whereas source reflects time to be 16:07.' answered with 'time corrected' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:41:42
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 23:41:36
User entered '16:07' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 23:41:36
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:28:23
User opened query 'Please confirm Time of Assessment inconsistent with source whereas source reflects time to be 16:07.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 21:27:49
User entered '15:45'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered '18 Aug 2020 16:07'	System	14 Jan 2021 23:41:36
User entered '18 Aug 2020 15:45'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '98.3' F	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '87'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'bpm'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'breaths/min'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '118'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'mmHg'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '84'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'mmHg'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:53:57
User entered '173.0' cm	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 21:53:57
User entered '81.2' kg	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:26:25
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 21:11:08
User entered '17:33'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered '18 Aug 2020 17:33'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '98.6' F	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '76'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'bpm'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'breaths/min'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '118'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'mmHg'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:23
User entered '75'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'mmHg'	System	19 Aug 2020 21:11:08

US3592226

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:42:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:11:17

US3592226

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:42:27
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:11:17

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

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 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:47
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:47
User entered '17:02'	(b) (4), (b) (6)	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered '18 Aug 2020 17:02'	System	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:47
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:28:47
User entered 'ONCE'	System	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 22:07:14

US3592226

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:11:54

US3592226

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:50
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:11:54

US3592226

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:50
User entered '16:25'	(b) (4), (b) (6)	19 Aug 2020 21:11:54

US3592226

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered '18 Aug 2020 16:25'	System	19 Aug 2020 21:11:54

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:53
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:53
User entered '16:17'	(b) (4), (b) (6)	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered '18 Aug 2020 16:17'	System	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:53
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:53
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered empty.	System	19 Aug 2020 21:12:17

US3592226

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:28:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:12:31

US3592226

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'l'	System	19 Aug 2020 21:12:31

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:40:32', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137c5525-868c-4424-8e03-741e5dc9b228'	System	18 Aug 2020 22:40:52
User entered 'Yes (Y)'	System	18 Aug 2020 22:40:52

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:40:38', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137c5525-868c-4424-8e03-741e5dc9b228' User entered '98.6'	System	18 Aug 2020 22:40:52
	System	18 Aug 2020 22:40:52

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:40:42', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137c5525-868c-4424-8e03-741e5dc9b228'	System	18 Aug 2020 22:40:52
User entered 'No (N)'	System	18 Aug 2020 22:40:52

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:40:49', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137c5525-868c-4424-8e03-741e5dc9b228'	System	18 Aug 2020 22:40:52
User entered '18 Aug 2020 17:40'	System	18 Aug 2020 22:40:52

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 17:22'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 19:52'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 20:47'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 2'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:09', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cbf93b0-6a73-4765-9ad0-0fb0fe284613'	System	19 Aug 2020 19:04:24
User entered 'Yes (Y)'	System	19 Aug 2020 19:04:24

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:15', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cbf93b0-6a73-4765-9ad0-0fb0fe284613' User entered '98.3'	System	19 Aug 2020 19:04:24
	System	19 Aug 2020 19:04:24

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:18', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cbf93b0-6a73-4765-9ad0-0fb0fe284613'	System	19 Aug 2020 19:04:24
User entered 'No (N)'	System	19 Aug 2020 19:04:24

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cbf93b0-6a73-4765-9ad0-0fb0fe284613'	System	19 Aug 2020 19:04:24
User entered '19 Aug 2020 14:04'	System	19 Aug 2020 19:04:24

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 3'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:06:49', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '53c213c5-e855-46f7-8188-6699f21c3617'	System	20 Aug 2020 22:07:13
User entered 'Yes (Y)'	System	20 Aug 2020 22:07:13

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:02', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '53c213c5-e855-46f7-8188-6699f21c3617' User entered '97.9'	System	20 Aug 2020 22:07:13
	System	20 Aug 2020 22:07:13

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:05', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '53c213c5-e855-46f7-8188-6699f21c3617'	System	20 Aug 2020 22:07:13
User entered 'No (N)'	System	20 Aug 2020 22:07:13

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:08', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '53c213c5-e855-46f7-8188-6699f21c3617'	System	20 Aug 2020 22:07:13
User entered '20 Aug 2020 17:07'	System	20 Aug 2020 22:07:13

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 4'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:17', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '811bf952-1236-4f85-8519-a41b2ea63ca2'	System	21 Aug 2020 20:58:29
User entered 'Yes (Y)'	System	21 Aug 2020 20:58:29

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:22', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '811bf952-1236-4f85-8519-a41b2ea63ca2'	System	21 Aug 2020 20:58:29
User entered '97.0'	System	21 Aug 2020 20:58:29

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '811bf952-1236-4f85-8519-a41b2ea63ca2'	System	21 Aug 2020 20:58:29
User entered 'No (N)'	System	21 Aug 2020 20:58:29

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:26', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '811bf952-1236-4f85-8519-a41b2ea63ca2'	System	21 Aug 2020 20:58:29
User entered '21 Aug 2020 15:58'	System	21 Aug 2020 20:58:29

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 5'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:14:43', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '683ac329-ae4e-4b15-b4d1-d823d0a8c2c0'	System	22 Aug 2020 20:14:54
User entered 'Yes (Y)'	System	22 Aug 2020 20:14:54

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:14:47', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '683ac329-ae4e-4b15-b4d1-d823d0a8c2c0' User entered '98.2'	System	22 Aug 2020 20:14:54
	System	22 Aug 2020 20:14:54

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:14:49', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '683ac329-ae4e-4b15-b4d1-d823d0a8c2c0'	System	22 Aug 2020 20:14:54
User entered 'No (N)'	System	22 Aug 2020 20:14:54

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:14:51', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '683ac329-ae4e-4b15-b4d1-d823d0a8c2c0'	System	22 Aug 2020 20:14:54
User entered '22 Aug 2020 15:14'	System	22 Aug 2020 20:14:54

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 6'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:05:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5e1233f-ee62-4522-999f-cd6da69397ef'	System	23 Aug 2020 20:06:34
User entered 'Yes (Y)'	System	23 Aug 2020 20:06:34

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:05:33', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5e1233f-ee62-4522-999f-cd6da69397ef' User entered '96.6'	System	23 Aug 2020 20:06:34
	System	23 Aug 2020 20:06:34

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:06:31', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5e1233f-ee62-4522-999f-cd6da69397ef'	System	23 Aug 2020 20:06:34
User entered 'No (N)'	System	23 Aug 2020 20:06:34

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:06:33', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5e1233f-ee62-4522-999f-cd6da69397ef'	System	23 Aug 2020 20:06:34
User entered '23 Aug 2020 15:06'	System	23 Aug 2020 20:06:34

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 7'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:39:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '23f2eba0-f3eb-452b-9eb5-ab6809c8923c'	System	24 Aug 2020 20:39:53
User entered 'Yes (Y)'	System	24 Aug 2020 20:39:53

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:39:44', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '23f2eba0-f3eb-452b-9eb5-ab6809c8923c'	System	24 Aug 2020 20:39:53
User entered '97.0'	System	24 Aug 2020 20:39:53

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:39:46', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '23f2eba0-f3eb-452b-9eb5-ab6809c8923c'	System	24 Aug 2020 20:39:53
User entered 'No (N)'	System	24 Aug 2020 20:39:53

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:39:48', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '23f2eba0-f3eb-452b-9eb5-ab6809c8923c'	System	24 Aug 2020 20:39:53
User entered '24 Aug 2020 15:39'	System	24 Aug 2020 20:39:53

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:40:57', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd0237d02-0316-4bb7-97a9-012b5a7bdaae'	System	18 Aug 2020 22:41:12
User entered 'None (1)'	System	18 Aug 2020 22:41:12

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd0237d02-0316-4bb7-97a9-012b5a7bdaae'	System	18 Aug 2020 22:41:12
User entered 'No (N)'	System	18 Aug 2020 22:41:12

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:03', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd0237d02-0316-4bb7-97a9-012b5a7bdaae'	System	18 Aug 2020 22:41:12
User entered 'No (N)'	System	18 Aug 2020 22:41:12

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:06', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd0237d02-0316-4bb7-97a9-012b5a7bdaae'	System	18 Aug 2020 22:41:12
User entered 'None (1)'	System	18 Aug 2020 22:41:12

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:09', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd0237d02-0316-4bb7-97a9-012b5a7bdaae'	System	18 Aug 2020 22:41:12
User entered '18 Aug 2020 17:41'	System	18 Aug 2020 22:41:12

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 17:22'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 19:52'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 20:47'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 2'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:29', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2e6b4560-ca7b-43dc-9d96-b21ece7123fd'	System	19 Aug 2020 19:04:44
User entered 'None (1)'	System	19 Aug 2020 19:04:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:32', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2e6b4560-ca7b-43dc-9d96-b21ece7123fd'	System	19 Aug 2020 19:04:44
User entered 'No (N)'	System	19 Aug 2020 19:04:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:34', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2e6b4560-ca7b-43dc-9d96-b21ece7123fd'	System	19 Aug 2020 19:04:44
User entered 'No (N)'	System	19 Aug 2020 19:04:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2e6b4560-ca7b-43dc-9d96-b21ece7123fd'	System	19 Aug 2020 19:04:44
User entered 'None (1)'	System	19 Aug 2020 19:04:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:39', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2e6b4560-ca7b-43dc-9d96-b21ece7123fd'	System	19 Aug 2020 19:04:44
User entered '19 Aug 2020 14:04'	System	19 Aug 2020 19:04:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 3'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:12', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6c520970-71bd-46a9-bcd0-d20951451166'	System	20 Aug 2020 22:07:26
User entered 'None (1)'	System	20 Aug 2020 22:07:26

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:16', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6c520970-71bd-46a9-bcd0-d20951451166'	System	20 Aug 2020 22:07:26
User entered 'No (N)'	System	20 Aug 2020 22:07:26

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:18', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6c520970-71bd-46a9-bcd0-d20951451166'	System	20 Aug 2020 22:07:26
User entered 'No (N)'	System	20 Aug 2020 22:07:26

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6c520970-71bd-46a9-bcd0-d20951451166'	System	20 Aug 2020 22:07:26
User entered 'None (1)'	System	20 Aug 2020 22:07:26

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6c520970-71bd-46a9-bcd0-d20951451166'	System	20 Aug 2020 22:07:26
User entered '20 Aug 2020 17:07'	System	20 Aug 2020 22:07:26

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 4'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:30', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2a034ebf-69ba-4d41-8b17-73d4daa71f94'	System	21 Aug 2020 20:58:44
User entered 'None (1)'	System	21 Aug 2020 20:58:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:33', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2a034ebf-69ba-4d41-8b17-73d4daa71f94'	System	21 Aug 2020 20:58:44
User entered 'No (N)'	System	21 Aug 2020 20:58:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:35', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2a034ebf-69ba-4d41-8b17-73d4daa71f94'	System	21 Aug 2020 20:58:44
User entered 'No (N)'	System	21 Aug 2020 20:58:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2a034ebf-69ba-4d41-8b17-73d4daa71f94'	System	21 Aug 2020 20:58:44
User entered 'None (1)'	System	21 Aug 2020 20:58:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:39', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2a034ebf-69ba-4d41-8b17-73d4daa71f94'	System	21 Aug 2020 20:58:44
User entered '21 Aug 2020 15:58'	System	21 Aug 2020 20:58:44

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 5'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:14:54', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '1006175c-b3c4-4768-bed1-2fedb4405be4'	System	22 Aug 2020 20:15:07
User entered 'None (1)'	System	22 Aug 2020 20:15:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:14:57', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '1006175c-b3c4-4768-bed1-2fedb4405be4'	System	22 Aug 2020 20:15:07
User entered 'No (N)'	System	22 Aug 2020 20:15:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:14:59', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '1006175c-b3c4-4768-bed1-2fedb4405be4'	System	22 Aug 2020 20:15:07
User entered 'No (N)'	System	22 Aug 2020 20:15:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:01', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '1006175c-b3c4-4768-bed1-2fedb4405be4'	System	22 Aug 2020 20:15:07
User entered 'None (1)'	System	22 Aug 2020 20:15:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:03', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '1006175c-b3c4-4768-bed1-2fedb4405be4'	System	22 Aug 2020 20:15:07
User entered '22 Aug 2020 15:15'	System	22 Aug 2020 20:15:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 6'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:38:47', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '057e29dc-4481-408f-bcaa-199d6ceee1af'	System	23 Aug 2020 20:39:07
User entered 'None (1)'	System	23 Aug 2020 20:39:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:38:50', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '057e29dc-4481-408f-bcaa-199d6ceee1af'	System	23 Aug 2020 20:39:07
User entered 'No (N)'	System	23 Aug 2020 20:39:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:38:52', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '057e29dc-4481-408f-bcaa-199d6ceee1af'	System	23 Aug 2020 20:39:07
User entered 'No (N)'	System	23 Aug 2020 20:39:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:38:57', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '057e29dc-4481-408f-bcaa-199d6ceee1af'	System	23 Aug 2020 20:39:07
User entered 'None (1)'	System	23 Aug 2020 20:39:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:01', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '057e29dc-4481-408f-bcaa-199d6ceee1af'	System	23 Aug 2020 20:39:07
User entered '23 Aug 2020 15:39'	System	23 Aug 2020 20:39:07

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 7'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:39:54', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cce5868-1a33-42f3-829d-e74e0e9cecaf'	System	24 Aug 2020 20:40:08
User entered 'None (1)'	System	24 Aug 2020 20:40:08

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:39:57', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cce5868-1a33-42f3-829d-e74e0e9cecaf'	System	24 Aug 2020 20:40:08
User entered 'No (N)'	System	24 Aug 2020 20:40:08

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:39:59', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cce5868-1a33-42f3-829d-e74e0e9cecaf'	System	24 Aug 2020 20:40:08
User entered 'No (N)'	System	24 Aug 2020 20:40:08

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:02', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cce5868-1a33-42f3-829d-e74e0e9cecaf'	System	24 Aug 2020 20:40:08
User entered 'None (1)'	System	24 Aug 2020 20:40:08

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:04', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9cce5868-1a33-42f3-829d-e74e0e9cecaf'	System	24 Aug 2020 20:40:08
User entered '24 Aug 2020 15:40'	System	24 Aug 2020 20:40:08

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:16', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered 'None (0)'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:19', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered 'None (0)'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered 'None (0)'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered 'None (0)'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:26', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered 'None (0)'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:28', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered 'None (0)'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:36', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered 'No (N)'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-18T17:41:38', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '545868eb-d8ea-456d-806b-abf3a6fb52a0'	System	18 Aug 2020 22:41:40
User entered '18 Aug 2020 17:41'	System	18 Aug 2020 22:41:40

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 17:22'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 19:52'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Aug 2020 20:47'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 2'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:45', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered 'None (0)'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:49', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered 'None (0)'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:51', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered 'None (0)'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:53', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered 'None (0)'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:55', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered 'None (0)'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:04:57', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered 'None (0)'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered 'No (N)'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-19T14:05:02', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2c257188-e8f2-4d2a-8a9b-72bd995eee74'	System	19 Aug 2020 19:05:06
User entered '19 Aug 2020 14:05'	System	19 Aug 2020 19:05:06

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 3'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:28', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered 'None (0)'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:30', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered 'None (0)'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:32', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered 'None (0)'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:35', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered 'None (0)'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:39', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered 'None (0)'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:42', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered 'None (0)'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:44', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered 'No (N)'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-20T17:07:46', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '941ff96a-a0bb-41cb-90c5-8a6f21ef0283'	System	20 Aug 2020 22:07:47
User entered '20 Aug 2020 17:07'	System	20 Aug 2020 22:07:47

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 4'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:42', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered 'None (0)'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:44', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered 'None (0)'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:46', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered 'None (0)'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:47', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered 'None (0)'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:49', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered 'None (0)'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:51', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered 'None (0)'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:52', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered 'No (N)'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-21T15:58:54', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4b414e0-5541-424d-a50f-cda629b343ff'	System	21 Aug 2020 20:59:01
User entered '21 Aug 2020 15:58'	System	21 Aug 2020 20:59:01

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 5'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:07', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbee76'	System	22 Aug 2020 20:15:23
User entered 'None (0)'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:08', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbee76'	System	22 Aug 2020 20:15:23
User entered 'None (0)'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:10', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbee76'	System	22 Aug 2020 20:15:23
User entered 'None (0)'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:12', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbec76'	System	22 Aug 2020 20:15:23
User entered 'None (0)'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbee76'	System	22 Aug 2020 20:15:23
User entered 'None (0)'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:15', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbee76'	System	22 Aug 2020 20:15:23
User entered 'None (0)'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:19', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbee76'	System	22 Aug 2020 20:15:23
User entered 'No (N)'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-22T15:15:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bdfc7472-0be6-4ed0-b0f4-fe8575fbec76'	System	22 Aug 2020 20:15:23
User entered '22 Aug 2020 15:15'	System	22 Aug 2020 20:15:23

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 6'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:15', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered 'None (0)'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:17', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered 'None (0)'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:18', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered 'None (0)'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:20', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered 'None (0)'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered 'None (0)'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:23', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered 'None (0)'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered 'No (N)'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-23T15:39:29', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '137b3aed-bddb-4dcd-b297-fdf7fb25e6bf'	System	23 Aug 2020 20:39:30
User entered '23 Aug 2020 15:39'	System	23 Aug 2020 20:39:30

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 7'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:12', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered 'None (0)'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered 'None (0)'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:16', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered 'None (0)'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

JOINT ACES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:18', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered 'None (0)'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:20', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered 'None (0)'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:22', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered 'None (0)'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered 'No (N)'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-08-24T15:40:26', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'db419838-f6ff-4b60-ab32-3c5a8f170621'	System	24 Aug 2020 20:40:29
User entered '24 Aug 2020 15:40'	System	24 Aug 2020 20:40:29

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 22:07:14

US3592226

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 16:59:26

US3592226

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:17
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 16:59:26

US3592226

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Aug 2020 16:59:26

US3592226

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:17
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 16:59:26

US3592226

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 16:59:31

US3592226

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'l'	System	27 Aug 2020 16:59:31

US3592226

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:40:01

US3592226

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:46
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 21:40:01

US3592226

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 21:40:01

US3592226

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:46
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 21:40:01

US3592226

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:40:08

US3592226

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:35
User entered 'l'	System	02 Sep 2020 21:40:08

US3592226

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:33:13

US3592226

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:05
User entered '9 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:33:13

US3592226

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 20:33:13

US3592226

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:05
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:33:13

US3592226

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 22:10:48

US3592226

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:31
User entered 'I'	System	15 Sep 2020 22:10:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:35:22

US3592226

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:25
User entered '15 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:35:22

US3592226

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:30:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Sep 2020 20:35:22

US3592226

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'VISIT2'	System	16 Sep 2020 20:35:22

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User accepted default value 'Pre-Dose (PREDOSE)'		16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '15 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '16:24'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered '15 Sep 2020 16:24'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '98.6' F	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '87'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'bpm'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '15'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'breaths/min'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '119'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'mmHg'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '82'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'mmHg'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User accepted default value 'Post-Dose (POSTDOSE)'		16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '15 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '17:42'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered '15 Sep 2020 17:42'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '100.0' F	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '80'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'bpm'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '16'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'breaths/min'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '110'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'mmHg'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:31:57
User entered '77'	(b) (4), (b) (6)	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'mmHg'	System	16 Sep 2020 20:41:24

US3592226

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:36:15

US3592226

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:08:24
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 20:36:15

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:08
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:08
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:08
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:08
User entered '17:09'	(b) (4), (b) (6)	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered '15 Sep 2020 17:09'	System	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:08
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
DataPoint Verified.		12 Jan 2021 21:32:08
User entered 'ONCE'	System	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 22:11:06

US3592226

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:37:40

US3592226

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:12
User entered '15 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:37:40

US3592226

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:12
User entered '16:47'	(b) (4), (b) (6)	16 Sep 2020 20:37:40

US3592226

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered '15 Sep 2020 16:47'	System	16 Sep 2020 20:37:40

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:16
User entered '15 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:16
User entered '16:29'	(b) (4), (b) (6)	16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered '15 Sep 2020 16:29'	System	16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:16
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:38

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered empty.	System	16 Sep 2020 20:38:48

US3592226

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:41:33

US3592226

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'I'	System	16 Sep 2020 20:41:33

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:15', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f04193a6-3988-4f8f-87b6-e616f102bca2'	System	15 Sep 2020 22:39:28
User entered 'Yes (Y)'	System	15 Sep 2020 22:39:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:19', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f04193a6-3988-4f8f-87b6-e616f102bca2'	System	15 Sep 2020 22:39:28
User entered '100.0'	System	15 Sep 2020 22:39:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:22', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f04193a6-3988-4f8f-87b6-e616f102bca2'	System	15 Sep 2020 22:39:28
User entered 'No (N)'	System	15 Sep 2020 22:39:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:26', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f04193a6-3988-4f8f-87b6-e616f102bca2'	System	15 Sep 2020 22:39:28
User entered '15 Sep 2020 17:39'	System	15 Sep 2020 22:39:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 17:29'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 19:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 20:54'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 2'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:00:40', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '7118f6a1-33ad-4d0c-94cd-31a6bed56dc1'	System	16 Sep 2020 21:00:55
User entered 'Yes (Y)'	System	16 Sep 2020 21:00:55

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:00:45', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '7118f6a1-33ad-4d0c-94cd-31a6bed56dc1' User entered '99.2'	System	16 Sep 2020 21:00:55
	System	16 Sep 2020 21:00:55

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:00:50', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '7118f6a1-33ad-4d0c-94cd-31a6bed56dc1'	System	16 Sep 2020 21:00:55
User entered 'No (N)'	System	16 Sep 2020 21:00:55

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:00:52', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '7118f6a1-33ad-4d0c-94cd-31a6bed56dc1'	System	16 Sep 2020 21:00:55
User entered '16 Sep 2020 16:00'	System	16 Sep 2020 21:00:55

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 3'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:08', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e2ba53ab-704b-48ad-9585-8fc8a1407e67'	System	17 Sep 2020 20:35:21
User entered 'Yes (Y)'	System	17 Sep 2020 20:35:21

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:12', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e2ba53ab-704b-48ad-9585-8fc8a1407e67' User entered '97.1'	System	17 Sep 2020 20:35:21
	System	17 Sep 2020 20:35:21

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:17', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e2ba53ab-704b-48ad-9585-8fc8a1407e67'	System	17 Sep 2020 20:35:21
User entered 'No (N)'	System	17 Sep 2020 20:35:21

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:19', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e2ba53ab-704b-48ad-9585-8fc8a1407e67'	System	17 Sep 2020 20:35:21
User entered '17 Sep 2020 15:35'	System	17 Sep 2020 20:35:21

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 4'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:07:51', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '5ffb8590-a8b8-4f66-a26d-92e39e5c9295'	System	18 Sep 2020 17:08:10
User entered 'Yes (Y)'	System	18 Sep 2020 17:08:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:07:55', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '5ffb8590-a8b8-4f66-a26d-92e39e5c9295' User entered '97.3'	System	18 Sep 2020 17:08:10
	System	18 Sep 2020 17:08:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:06', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '5ffb8590-a8b8-4f66-a26d-92e39e5c9295'	System	18 Sep 2020 17:08:10
User entered 'No (N)'	System	18 Sep 2020 17:08:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:08', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '5ffb8590-a8b8-4f66-a26d-92e39e5c9295'	System	18 Sep 2020 17:08:10
User entered '18 Sep 2020 12:08'	System	18 Sep 2020 17:08:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 5'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:16', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '3104dde8-c0ef-4614-8f45-a9fa5f6836e1'	System	19 Sep 2020 20:42:28
User entered 'Yes (Y)'	System	19 Sep 2020 20:42:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:20', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '3104dde8-c0ef-4614-8f45-a9fa5f6836e1' User entered '97.9'	System	19 Sep 2020 20:42:28
	System	19 Sep 2020 20:42:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '3104dde8-c0ef-4614-8f45-a9fa5f6836e1'	System	19 Sep 2020 20:42:28
User entered 'No (N)'	System	19 Sep 2020 20:42:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '3104dde8-c0ef-4614-8f45-a9fa5f6836e1' User entered '19 Sep 2020 15:42'	System	19 Sep 2020 20:42:28
	System	19 Sep 2020 20:42:28

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 6'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:02', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9d57436e-d469-41e8-9b85-ccfe57dfecc5'	System	20 Sep 2020 22:53:10
User entered 'Yes (Y)'	System	20 Sep 2020 22:53:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:05', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9d57436e-d469-41e8-9b85-ccfe57dfecc5'	System	20 Sep 2020 22:53:10
User entered '97.6'	System	20 Sep 2020 22:53:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:08', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9d57436e-d469-41e8-9b85-ccfe57dfecc5'	System	20 Sep 2020 22:53:10
User entered 'No (N)'	System	20 Sep 2020 22:53:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:09', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '9d57436e-d469-41e8-9b85-ccfe57dfecc5'	System	20 Sep 2020 22:53:10
User entered '20 Sep 2020 17:53'	System	20 Sep 2020 22:53:10

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 7'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f933a1de-f294-4a26-a3f9-c3367b543148'	System	21 Sep 2020 22:29:23
User entered 'Yes (Y)'	System	21 Sep 2020 22:29:23

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:17', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f933a1de-f294-4a26-a3f9-c3367b543148'	System	21 Sep 2020 22:29:23
User entered '98.4'	System	21 Sep 2020 22:29:23

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:19', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f933a1de-f294-4a26-a3f9-c3367b543148'	System	21 Sep 2020 22:29:23
User entered 'No (N)'	System	21 Sep 2020 22:29:23

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f933a1de-f294-4a26-a3f9-c3367b543148'	System	21 Sep 2020 22:29:23
User entered '21 Sep 2020 17:29'	System	21 Sep 2020 22:29:23

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:31', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '70ad4dc6-d68b-441f-81a2-ba3fd487c4e8'	System	15 Sep 2020 22:39:44
User entered 'None (1)'	System	15 Sep 2020 22:39:44

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:34', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '70ad4dc6-d68b-441f-81a2-ba3fd487c4e8'	System	15 Sep 2020 22:39:44
User entered 'No (N)'	System	15 Sep 2020 22:39:44

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '70ad4dc6-d68b-441f-81a2-ba3fd487c4e8'	System	15 Sep 2020 22:39:44
User entered 'No (N)'	System	15 Sep 2020 22:39:44

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:40', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '70ad4dc6-d68b-441f-81a2-ba3fd487c4e8'	System	15 Sep 2020 22:39:44
User entered 'None (1)'	System	15 Sep 2020 22:39:44

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:42', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '70ad4dc6-d68b-441f-81a2-ba3fd487c4e8'	System	15 Sep 2020 22:39:44
User entered '15 Sep 2020 17:39'	System	15 Sep 2020 22:39:44

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 17:29'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 19:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 20:54'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 2'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:00:58', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e4ff982c-7134-4088-8b67-1df60360c6d7'	System	16 Sep 2020 21:01:10
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 21:01:10

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e4ff982c-7134-4088-8b67-1df60360c6d7'	System	16 Sep 2020 21:01:10
User entered 'No (N)'	System	16 Sep 2020 21:01:10

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:03', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e4ff982c-7134-4088-8b67-1df60360c6d7'	System	16 Sep 2020 21:01:10
User entered 'No (N)'	System	16 Sep 2020 21:01:10

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:06', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e4ff982c-7134-4088-8b67-1df60360c6d7'	System	16 Sep 2020 21:01:10
User entered 'None (1)'	System	16 Sep 2020 21:01:10

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:08', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e4ff982c-7134-4088-8b67-1df60360c6d7'	System	16 Sep 2020 21:01:10
User entered '16 Sep 2020 16:01'	System	16 Sep 2020 21:01:10

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 3'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0e76f9e8-5d64-45fc-9113-b576dbb49190'	System	17 Sep 2020 20:35:42
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 20:35:42

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:29', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0e76f9e8-5d64-45fc-9113-b576dbb49190'	System	17 Sep 2020 20:35:42
User entered 'No (N)'	System	17 Sep 2020 20:35:42

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:32', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0e76f9e8-5d64-45fc-9113-b576dbb49190'	System	17 Sep 2020 20:35:42
User entered 'No (N)'	System	17 Sep 2020 20:35:42

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:35', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0e76f9e8-5d64-45fc-9113-b576dbb49190'	System	17 Sep 2020 20:35:42
User entered 'None (1)'	System	17 Sep 2020 20:35:42

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:39', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0e76f9e8-5d64-45fc-9113-b576dbb49190'	System	17 Sep 2020 20:35:42
User entered '17 Sep 2020 15:35'	System	17 Sep 2020 20:35:42

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 4'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:11', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b46a3629-39e3-42e9-8d18-4d9184e10a89'	System	18 Sep 2020 17:08:20
User entered 'None (1)'	System	18 Sep 2020 17:08:20

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:13', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b46a3629-39e3-42e9-8d18-4d9184e10a89'	System	18 Sep 2020 17:08:20
User entered 'No (N)'	System	18 Sep 2020 17:08:20

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b46a3629-39e3-42e9-8d18-4d9184e10a89'	System	18 Sep 2020 17:08:20
User entered 'No (N)'	System	18 Sep 2020 17:08:20

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:16', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b46a3629-39e3-42e9-8d18-4d9184e10a89'	System	18 Sep 2020 17:08:20
User entered 'None (1)'	System	18 Sep 2020 17:08:20

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:18', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b46a3629-39e3-42e9-8d18-4d9184e10a89'	System	18 Sep 2020 17:08:20
User entered '18 Sep 2020 12:08'	System	18 Sep 2020 17:08:20

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 5'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:02', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5b21ed9-4e9b-4461-baac-647eeff4e312'	System	19 Sep 2020 20:42:14
User entered 'None (1)'	System	19 Sep 2020 20:42:14

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:04', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5b21ed9-4e9b-4461-baac-647eeff4e312'	System	19 Sep 2020 20:42:14
User entered 'No (N)'	System	19 Sep 2020 20:42:14

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:06', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5b21ed9-4e9b-4461-baac-647eeff4e312'	System	19 Sep 2020 20:42:14
User entered 'No (N)'	System	19 Sep 2020 20:42:14

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:09', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5b21ed9-4e9b-4461-baac-647eeff4e312'	System	19 Sep 2020 20:42:14
User entered 'None (1)'	System	19 Sep 2020 20:42:14

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:42:11', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'c5b21ed9-4e9b-4461-baac-647eeff4e312'	System	19 Sep 2020 20:42:14
User entered '19 Sep 2020 15:42'	System	19 Sep 2020 20:42:14

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 6'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2b69b455-85d7-494b-a874-4bc8ced0ca45'	System	20 Sep 2020 22:53:25
User entered 'None (1)'	System	20 Sep 2020 22:53:25

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:18', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2b69b455-85d7-494b-a874-4bc8ced0ca45'	System	20 Sep 2020 22:53:25
User entered 'No (N)'	System	20 Sep 2020 22:53:25

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:20', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2b69b455-85d7-494b-a874-4bc8ced0ca45'	System	20 Sep 2020 22:53:25
User entered 'No (N)'	System	20 Sep 2020 22:53:25

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:22', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2b69b455-85d7-494b-a874-4bc8ced0ca45'	System	20 Sep 2020 22:53:25
User entered 'None (1)'	System	20 Sep 2020 22:53:25

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2b69b455-85d7-494b-a874-4bc8ced0ca45'	System	20 Sep 2020 22:53:25
User entered '20 Sep 2020 17:53'	System	20 Sep 2020 22:53:25

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 7'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'dc28966f-81a9-4825-8dca-219e94460171'	System	21 Sep 2020 22:29:33
User entered 'None (1)'	System	21 Sep 2020 22:29:33

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:26', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'dc28966f-81a9-4825-8dca-219e94460171'	System	21 Sep 2020 22:29:33
User entered 'No (N)'	System	21 Sep 2020 22:29:33

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:28', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'dc28966f-81a9-4825-8dca-219e94460171'	System	21 Sep 2020 22:29:33
User entered 'No (N)'	System	21 Sep 2020 22:29:33

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:31', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'dc28966f-81a9-4825-8dca-219e94460171'	System	21 Sep 2020 22:29:33
User entered 'None (1)'	System	21 Sep 2020 22:29:33

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:32', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'dc28966f-81a9-4825-8dca-219e94460171'	System	21 Sep 2020 22:29:33
User entered '21 Sep 2020 17:29'	System	21 Sep 2020 22:29:33

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:46', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered 'None (0)'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:49', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered 'None (0)'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:52', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered 'None (0)'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:53', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered 'None (0)'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:58', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered 'None (0)'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:39:59', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered 'None (0)'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:40:02', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered 'No (N)'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-15T17:40:04', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '49582566-0a28-435d-829e-56d8c53d2c07'	System	15 Sep 2020 22:40:07
User entered '15 Sep 2020 17:40'	System	15 Sep 2020 22:40:07

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 17:29'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 19:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '15 Sep 2020 20:54'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 2'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:12', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered 'None (0)'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:13', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered 'None (0)'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:15', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered 'None (0)'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:17', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered 'None (0)'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:19', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered 'None (0)'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:20', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered 'None (0)'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:22', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered 'No (N)'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-16T16:01:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8a0305b9-9de5-407c-ab94-5f81da5c0d20'	System	16 Sep 2020 21:01:28
User entered '16 Sep 2020 16:01'	System	16 Sep 2020 21:01:28

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 3'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:45', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered 'None (0)'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:48', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered 'None (0)'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:50', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered 'None (0)'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:52', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered 'None (0)'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:54', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered 'None (0)'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:35:58', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered 'None (0)'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:36:01', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered 'No (N)'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-17T15:36:07', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32a46986-d940-41b5-a828-4ef7d4081c9e'	System	17 Sep 2020 20:36:11
User entered '17 Sep 2020 15:36'	System	17 Sep 2020 20:36:11

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 4'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered 'None (0)'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:23', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered 'None (0)'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:24', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered 'None (0)'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:25', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered 'None (0)'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered 'None (0)'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:29', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered 'None (0)'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:35', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered 'No (N)'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-18T12:08:36', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '95cf24f9-40ce-41b0-8331-a64609681506'	System	18 Sep 2020 17:08:37
User entered '18 Sep 2020 12:08'	System	18 Sep 2020 17:08:37

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 5'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:39', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered 'None (0)'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:40', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered 'None (0)'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:43', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered 'None (0)'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:44', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered 'None (0)'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:46', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered 'None (0)'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:51', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered 'None (0)'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:57', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered 'No (N)'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-19T15:41:59', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8b55c85-beb3-4c2d-b734-477b0186741b'	System	19 Sep 2020 20:42:03
User entered '19 Sep 2020 15:41'	System	19 Sep 2020 20:42:03

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 6'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered 'None (0)'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:29', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered 'None (0)'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:31', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered 'None (0)'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:33', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered 'None (0)'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:35', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered 'None (0)'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered 'None (0)'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:39', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered 'No (N)'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-20T17:53:41', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'ecdeb25f-ee4a-47c9-82ee-b75358b0d6cd'	System	20 Sep 2020 22:53:48
User entered '20 Sep 2020 17:53'	System	20 Sep 2020 22:53:48

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	15 Sep 2020 22:11:06
User entered 'Day 7'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:36', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered 'None (0)'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:38', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered 'None (0)'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:40', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered 'None (0)'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:42', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered 'None (0)'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:44', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered 'None (0)'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:46', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered 'None (0)'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:48', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered 'No (N)'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-09-21T17:29:50', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8744aad-5300-4c31-8b8b-1861ae8bded0'	System	21 Sep 2020 22:29:50
User entered '21 Sep 2020 17:29'	System	21 Sep 2020 22:29:50

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 22:11:06

US3592226

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 22:11:06

US3592226

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:32:08

US3592226

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:42
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:32:08

US3592226

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 21:32:08

US3592226

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:42
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:32:08

US3592226

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:32:23

US3592226

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'l'	System	24 Sep 2020 21:32:23

US3592226

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:15:51

US3592226

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:59
User entered '29 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:15:51

US3592226

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 21:15:51

US3592226

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:32:59
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:15:51

US3592226

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:15:54

US3592226

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'l'	System	30 Sep 2020 21:15:54

US3592226

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 20:26:00

US3592226

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:14
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 20:26:00

US3592226

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 20:26:00

US3592226

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:14
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 20:26:00

US3592226

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 20:26:19

US3592226

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'I'	System	06 Oct 2020 20:26:19

US3592226

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:14:59

US3592226

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:44
User entered '15 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:14:59

US3592226

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Oct 2020 16:14:59

US3592226

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'VISIT3'	System	16 Oct 2020 16:14:59

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered '15 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered '16:19'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered '15 Oct 2020 16:19'	System	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered '98.0' F	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered '75'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'bpm'	System	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'breaths/min'	System	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered '128'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'mmHg'	System	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:33:57
User entered '80'	(b) (4), (b) (6)	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'mmHg'	System	16 Oct 2020 16:15:29

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02

US3592226

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02

US3592226

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:00
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:15:50

US3592226

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:00
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:15:50

US3592226

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:16:01

US3592226

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:03
User closed query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 15-OCT-2020. However, this date matches V3D57 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:26:16
Query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 15-OCT-2020. However, this date matches V3D57 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' answered with 'Confirmed, unscheduled lab kit used for visit 3' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:55:41
User opened query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 15-OCT-2020. However, this date matches V3D57 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:28:11
User entered '15 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:16:01

US3592226

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:03
User entered '16:34'	(b) (4), (b) (6)	16 Oct 2020 16:16:01

US3592226

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered '15 Oct 2020 16:34'	System	16 Oct 2020 16:16:01

US3592226

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:00:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:18:30

US3592226

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'I'	System	16 Oct 2020 16:18:30

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 64'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-10-18T07:16:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8bbe2fc-8837-484d-bd90-b7c6d62da8b3'	System	18 Oct 2020 12:16:27
User entered 'No (N)'	System	18 Oct 2020 12:16:27

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-10-18T07:16:21', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8bbe2fc-8837-484d-bd90-b7c6d62da8b3'	System	18 Oct 2020 12:16:27
User entered 'No (N)'	System	18 Oct 2020 12:16:27

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-10-18T07:16:23', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd8bbe2fc-8837-484d-bd90-b7c6d62da8b3'	System	18 Oct 2020 12:16:27
User entered '18 Oct 2020 07:16:23'	System	18 Oct 2020 12:16:27

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 71'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-10-26T21:02:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6b3a7153-1ff5-4d3f-a50b-35cf078037f3'	System	27 Oct 2020 02:02:47
User entered 'No (N)'	System	27 Oct 2020 02:02:47

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-10-26T21:02:43', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6b3a7153-1ff5-4d3f-a50b-35cf078037f3'	System	27 Oct 2020 02:02:47
User entered 'No (N)'	System	27 Oct 2020 02:02:47

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-10-26T21:02:45', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6b3a7153-1ff5-4d3f-a50b-35cf078037f3' User entered '26 Oct 2020 21:02:45'	System	27 Oct 2020 02:02:47
	System	27 Oct 2020 02:02:47

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 78'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-02T11:06:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6e002cc7-2d65-4014-9049-676ae294a837'	System	02 Nov 2020 17:06:36
User entered 'No (N)'	System	02 Nov 2020 17:06:36

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-02T11:06:31', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6e002cc7-2d65-4014-9049-676ae294a837'	System	02 Nov 2020 17:06:36
User entered 'No (N)'	System	02 Nov 2020 17:06:36

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-02T11:06:34', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6e002cc7-2d65-4014-9049-676ae294a837'	System	02 Nov 2020 17:06:36
User entered '02 Nov 2020 11:06:34'	System	02 Nov 2020 17:06:36

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered 'Day 92'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-16T14:54:25', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6bd83453-3e79-42d1-b7be-6a95c32fff7e'	System	16 Nov 2020 20:54:36
User entered 'No (N)'	System	16 Nov 2020 20:54:36

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-16T14:54:28', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6bd83453-3e79-42d1-b7be-6a95c32fff7e'	System	16 Nov 2020 20:54:36
User entered 'No (N)'	System	16 Nov 2020 20:54:36

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-16T14:54:31', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '6bd83453-3e79-42d1-b7be-6a95c32fff7e'	System	16 Nov 2020 20:54:36
User entered '16 Nov 2020 14:54:31'	System	16 Nov 2020 20:54:36

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 22:07:14

US3592226

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:47:39
Data entry locked.	System	18 Aug 2020 22:07:14
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 22:07:14

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-11-22T12:10:11', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'fd4a352d-ed0d-4355-88e6-7e8d7e9c98f6'	System	22 Nov 2020 18:10:20
User entered 'No (N)'	System	22 Nov 2020 18:10:20

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2020-11-22T12:10:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'fd4a352d-ed0d-4355-88e6-7e8d7e9c98f6'	System	22 Nov 2020 18:10:20
User entered 'No (N)'	System	22 Nov 2020 18:10:20

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-22T12:10:16', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'fd4a352d-ed0d-4355-88e6-7e8d7e9c98f6'	System	22 Nov 2020 18:10:20
User entered '22 Nov 2020 12:10:16'	System	22 Nov 2020 18:10:20

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-11-30T19:55:09', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '526b6bfa-2d1d-421c-b674-67fa8e98798c'	System	01 Dec 2020 01:55:26
User entered 'No (N)'	System	01 Dec 2020 01:55:26

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2020-11-30T19:55:19', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '526b6bfa-2d1d-421c-b674-67fa8e98798c'	System	01 Dec 2020 01:55:26
User entered 'No (N)'	System	01 Dec 2020 01:55:26

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-11-30T19:55:23', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '526b6bfa-2d1d-421c-b674-67fa8e98798c'	System	01 Dec 2020 01:55:26
User entered '30 Nov 2020 19:55:23'	System	01 Dec 2020 01:55:26

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-12-05T04:44:28', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0f4d0344-aff0-417d-bc1c-25c2547fa9ba'	System	05 Dec 2020 10:44:43
User entered 'No (N)'	System	05 Dec 2020 10:44:43

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2020-12-05T04:44:34', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0f4d0344-aff0-417d-bc1c-25c2547fa9ba'	System	05 Dec 2020 10:44:43
User entered 'No (N)'	System	05 Dec 2020 10:44:43

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-12-05T04:44:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '0f4d0344-aff0-417d-bc1c-25c2547fa9ba' User entered '05 Dec 2020 04:44:37'	System	05 Dec 2020 10:44:43
	System	05 Dec 2020 10:44:43

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-12-10T08:06:02', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f50703f2-8f6f-4473-b2b6-6589bdfef0'	System	10 Dec 2020 14:06:13
User entered 'No (N)'	System	10 Dec 2020 14:06:13

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2020-12-10T08:06:07', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f50703f2-8f6f-4473-b2b6-6589bdfef0'	System	10 Dec 2020 14:06:13
User entered 'No (N)'	System	10 Dec 2020 14:06:13

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-12-10T08:06:10', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f50703f2-8f6f-4473-b2b6-6589bdfef0'	System	10 Dec 2020 14:06:13
User entered '10 Dec 2020 08:06:10'	System	10 Dec 2020 14:06:13

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-12-19T18:45:51', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8530d42-328e-472b-93c6-f8644fcd3a'	System	20 Dec 2020 00:46:01
User entered 'No (N)'	System	20 Dec 2020 00:46:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2020-12-19T18:45:55', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8530d42-328e-472b-93c6-f8644fcdfd3a'	System	20 Dec 2020 00:46:01
User entered 'No (N)'	System	20 Dec 2020 00:46:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-12-19T18:45:57', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'f8530d42-328e-472b-93c6-f8644fcd3a'	System	20 Dec 2020 00:46:01
User entered '19 Dec 2020 18:45:57'	System	20 Dec 2020 00:46:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-12-24T21:25:43', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b40b09d6-18ec-4b80-9f43-048778d7d430'	System	25 Dec 2020 03:25:50
User entered 'No (N)'	System	25 Dec 2020 03:25:50

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2020-12-24T21:25:45', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b40b09d6-18ec-4b80-9f43-048778d7d430'	System	25 Dec 2020 03:25:50
User entered 'No (N)'	System	25 Dec 2020 03:25:50

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2020-12-24T21:25:47', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b40b09d6-18ec-4b80-9f43-048778d7d430'	System	25 Dec 2020 03:25:50
User entered '24 Dec 2020 21:25:47'	System	25 Dec 2020 03:25:50

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-12-31T20:07:12', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '89cba392-42cf-4f01-87c9-0d7a591ffd85'	System	02 Jan 2021 12:47:17
User entered 'Yes (Y)'	System	02 Jan 2021 12:47:17

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2020-12-31T20:07:07', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '89cba392-42cf-4f01-87c9-0d7a591ffd85'	System	02 Jan 2021 12:47:17
User entered 'No (N)'	System	02 Jan 2021 12:47:17

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-12-31T20:07:05', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '89cba392-42cf-4f01-87c9-0d7a591ffd85'	System	02 Jan 2021 12:47:17
User entered 'No (N)'	System	02 Jan 2021 12:47:17

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2020-12-31T20:07:05', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '89cba392-42cf-4f01-87c9-0d7a591ffd85'	System	02 Jan 2021 12:47:17
User entered 'Yes (Y)'	System	02 Jan 2021 12:47:17

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Please 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 (75d6c8ffea29f449)', Time: '2020-12-31T20:07:04', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '89cba392-42cf-4f01-87c9-0d7a591ffd85'	System	02 Jan 2021 12:47:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 12:47:17

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-01-02T06:47:07', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '89cba392-42cf-4f01-87c9-0d7a591ffd85'	System	02 Jan 2021 12:47:17
User entered '02 Jan 2021 06:47:07'	System	02 Jan 2021 12:47:17

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-01-07T11:37:23', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2172b672-7fa8-433d-98a3-f7f25736836d'	System	07 Jan 2021 17:37:32
User entered 'No (N)'	System	07 Jan 2021 17:37:32

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-01-07T11:37:26', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2172b672-7fa8-433d-98a3-f7f25736836d'	System	07 Jan 2021 17:37:32
User entered 'No (N)'	System	07 Jan 2021 17:37:32

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-01-07T11:37:29', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '2172b672-7fa8-433d-98a3-f7f25736836d' User entered '07 Jan 2021 11:37:29'	System	07 Jan 2021 17:37:32

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-01-18T20:50:32', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'edbf4778-17bd-480b-9c66-cd46b65ab37b'	System	19 Jan 2021 02:50:49
User entered 'No (N)'	System	19 Jan 2021 02:50:49

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-01-18T20:50:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'edbf4778-17bd-480b-9c66-cd46b65ab37b'	System	19 Jan 2021 02:50:49
User entered 'No (N)'	System	19 Jan 2021 02:50:49

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-01-18T20:50:45', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'edbf4778-17bd-480b-9c66-cd46b65ab37b'	System	19 Jan 2021 02:50:49
User entered '18 Jan 2021 20:50:45'	System	19 Jan 2021 02:50:49

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-01-21T11:07:23', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd7685d11-ada6-4c02-965f-37f9e21b287e'	System	21 Jan 2021 17:07:33
User entered 'No (N)'	System	21 Jan 2021 17:07:33

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-01-21T11:07:26', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd7685d11-ada6-4c02-965f-37f9e21b287e'	System	21 Jan 2021 17:07:33
User entered 'No (N)'	System	21 Jan 2021 17:07:33

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-01-21T11:07:28', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'd7685d11-ada6-4c02-965f-37f9e21b287e'	System	21 Jan 2021 17:07:33
User entered '21 Jan 2021 11:07:28'	System	21 Jan 2021 17:07:33

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-01-29T18:45:09', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '846b5011-4ebf-408c-ab44-bc765b1cfdb2'	System	30 Jan 2021 00:45:19
User entered 'No (N)'	System	30 Jan 2021 00:45:19

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-01-29T18:45:12', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '846b5011-4ebf-408c-ab44-bc765b1cfdb2'	System	30 Jan 2021 00:45:19
User entered 'No (N)'	System	30 Jan 2021 00:45:19

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-01-29T18:45:14', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '846b5011-4ebf-408c-ab44-bc765b1cfdb2'	System	30 Jan 2021 00:45:19
User entered '29 Jan 2021 18:45:14'	System	30 Jan 2021 00:45:19

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-02-05T20:34:52', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'afe4475f-6686-4fc4-afa6-b0096e0d8b1b'	System	06 Feb 2021 02:35:10
User entered 'No (N)'	System	06 Feb 2021 02:35:10

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-02-05T20:34:56', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'afe4475f-6686-4fc4-afa6-b0096e0d8b1b'	System	06 Feb 2021 02:35:10
User entered 'No (N)'	System	06 Feb 2021 02:35:10

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-02-05T20:34:58', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'afe4475f-6686-4fc4-afa6-b0096e0d8b1b'	System	06 Feb 2021 02:35:10
User entered '05 Feb 2021 20:34:58'	System	06 Feb 2021 02:35:10

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-02-13T21:43:27', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '242a49b6-0deb-4623-a9c6-5e8aa6424878'	System	14 Feb 2021 03:43:35
User entered 'No (N)'	System	14 Feb 2021 03:43:35

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-02-13T21:43:29', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '242a49b6-0deb-4623-a9c6-5e8aa6424878'	System	14 Feb 2021 03:43:35
User entered 'No (N)'	System	14 Feb 2021 03:43:35

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-02-13T21:43:31', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '242a49b6-0deb-4623-a9c6-5e8aa6424878'	System	14 Feb 2021 03:43:35
User entered '13 Feb 2021 21:43:31'	System	14 Feb 2021 03:43:35

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-02-18T00:01:33', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '853bea6b-7009-479e-ab0d-f374bcd9e684'	System	18 Feb 2021 06:02:06
User entered 'No (N)'	System	18 Feb 2021 06:02:06

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-02-18T00:01:36', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '853bea6b-7009-479e-ab0d-f374bcd9e684'	System	18 Feb 2021 06:02:06
User entered 'No (N)'	System	18 Feb 2021 06:02:06

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-02-18T00:01:37', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '853bea6b-7009-479e-ab0d-f374bcd9e684' User entered '18 Feb 2021 00:01:37'	System	18 Feb 2021 06:02:06
	System	18 Feb 2021 06:02:06

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-02-28T12:01:21-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32e5d4c6-e22e-4dd2-861e-7d0f235cff4c' User entered 'No (N)'	System	28 Feb 2021 18:03:13

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-02-28T12:01:31-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32e5d4c6-e22e-4dd2-861e-7d0f235cff4c' User entered 'No (N)'	System	28 Feb 2021 18:03:13

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-02-28T12:01:35-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '32e5d4c6-e22e-4dd2-861e-7d0f235cff4c'	System	28 Feb 2021 18:03:13
User entered '28 Feb 2021 12:01:35'	System	28 Feb 2021 18:03:13

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-03-04T00:41:20-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e96b4a91-6e9e-4b56-8052-752fea78dd3b' User entered 'No (N)'	System	04 Mar 2021 06:41:35
	System	04 Mar 2021 06:41:35

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-03-04T00:41:23-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e96b4a91-6e9e-4b56-8052-752fea78dd3b' User entered 'No (N)'	System	04 Mar 2021 06:41:35

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-03-04T00:41:31-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e96b4a91-6e9e-4b56-8052-752fea78dd3b' User entered '04 Mar 2021 00:41:31'	System	04 Mar 2021 06:41:35
	System	04 Mar 2021 06:41:35

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-03-12T13:50:18-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b83b6a61-ee87-4b99-b591-18c706c5bcef' User entered 'No (N)'	System	12 Mar 2021 19:50:29
	System	12 Mar 2021 19:50:29

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-03-12T13:50:23-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b83b6a61-ee87-4b99-b591-18c706c5bcef' User entered 'No (N)'	System	12 Mar 2021 19:50:29

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-03-12T13:50:25-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'b83b6a61-ee87-4b99-b591-18c706c5bcef' User entered '12 Mar 2021 13:50:25'	System	12 Mar 2021 19:50:29
	System	12 Mar 2021 19:50:29

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-03-19T08:40:46-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4bf0fda-0142-48c1-9e5f-b4a9f1e558bc' User entered 'No (N)'	System	19 Mar 2021 13:40:53

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-03-19T08:40:48-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4bf0fda-0142-48c1-9e5f-b4a9fle558bc'	System	19 Mar 2021 13:40:53
User entered 'No (N)'	System	19 Mar 2021 13:40:53

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-03-19T08:40:50-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4bf0fda-0142-48c1-9e5f-b4a9f1e558bc' User entered '19 Mar 2021 08:40:50'	System	19 Mar 2021 13:40:53

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-03-25T20:46:53-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e0bde2f2-4295-40ef-b219-f62920d0740e'	System	26 Mar 2021 01:47:01
User entered 'No (N)'	System	26 Mar 2021 01:47:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-03-25T20:46:56-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e0bde2f2-4295-40ef-b219-f62920d0740e'	System	26 Mar 2021 01:47:01
User entered 'No (N)'	System	26 Mar 2021 01:47:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-03-25T20:46:58-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'e0bde2f2-4295-40ef-b219-f62920d0740e' User entered '25 Mar 2021 20:46:58'	System	26 Mar 2021 01:47:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-04-01T17:07:19-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4acd8b2-1b22-41bd-a046-372043a5da89' User entered 'No (N)'	System	01 Apr 2021 22:10:28
	System	01 Apr 2021 22:10:28

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-04-01T17:07:21-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4acd8b2-1b22-41bd-a046-372043a5da89' User entered 'No (N)'	System	01 Apr 2021 22:10:28

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-04-01T17:07:23-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'a4acd8b2-1b22-41bd-a046-372043a5da89' User entered '01 Apr 2021 17:07:23'	System	01 Apr 2021 22:10:28
	System	01 Apr 2021 22:10:28

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-04-08T09:53:32-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '676dc631-025f-4868-a48c-4838c534043f' User entered 'No (N)'	System	08 Apr 2021 14:53:41

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-04-08T09:53:34-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '676dc631-025f-4868-a48c-4838c534043f' User entered 'No (N)'	System	08 Apr 2021 14:53:41

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-04-08T09:53:37-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '676dc631-025f-4868-a48c-4838c534043f' User entered '08 Apr 2021 09:53:37'	System	08 Apr 2021 14:53:41
	System	08 Apr 2021 14:53:41

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-04-18T18:15:01-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8df661e3-1cc2-4c39-b6dc-996d1c6b984a' User entered 'No (N)'	System	18 Apr 2021 23:15:08
	System	18 Apr 2021 23:15:08

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-04-18T18:15:03-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8df661e3-1cc2-4c39-b6dc-996d1c6b984a' User entered 'No (N)'	System	18 Apr 2021 23:15:08

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-04-18T18:15:05-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '8df661e3-1cc2-4c39-b6dc-996d1c6b984a'	System	18 Apr 2021 23:15:08
User entered '18 Apr 2021 18:15:05'	System	18 Apr 2021 23:15:08

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-04-22T17:03:51-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '4b779c63-901d-40a7-96a5-85e159531e99'	System	22 Apr 2021 22:07:01
User entered 'No (N)'	System	22 Apr 2021 22:07:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-04-22T17:03:53-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '4b779c63-901d-40a7-96a5-85e159531e99'	System	22 Apr 2021 22:07:01
User entered 'No (N)'	System	22 Apr 2021 22:07:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-04-22T17:03:55-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '4b779c63-901d-40a7-96a5-85e159531e99'	System	22 Apr 2021 22:07:01
User entered '22 Apr 2021 17:03:55'	System	22 Apr 2021 22:07:01

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[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 (75d6c8ffea29f449)', Time: '2021-04-29T00:39:26-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '11397a7b-f936-42f0-ab14-1b54e1141430' User entered 'No (N)'	System	29 Apr 2021 05:39:33
	System	29 Apr 2021 05:39:33

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

Have you been exposed to someone with 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 (75d6c8ffea29f449)', Time: '2021-04-29T00:39:27-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '11397a7b-f936-42f0-ab14-1b54e1141430' User entered 'No (N)'	System	29 Apr 2021 05:39:33

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-04-29T00:39:29-05:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: '11397a7b-f936-42f0-ab14-1b54e1141430' User entered '29 Apr 2021 00:39:29'	System	29 Apr 2021 05:39:33
	System	29 Apr 2021 05:39:33

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:36:36

US3592226

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:36:36
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:36:36

US3592226

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:20:38

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 20:27:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-02-28T12:01:40-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bc2144d3-b449-4887-8e3c-b1dacdab163c'	System	28 Feb 2021 18:03:39
User entered 'No (N)'	System	28 Feb 2021 18:03:39

US3592226

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:20:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:27:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (75d6c8ffea29f449)', Time: '2021-02-28T12:01:46-06:00', User OID: 'PatientReportedOutcome (US3592226)', ODM File OID: 'bc2144d3-b449-4887-8e3c-b1dacdab163c' User entered '28 Feb 2021 12:01:46'	System	28 Feb 2021 18:03:39
	System	28 Feb 2021 18:03:39

US3592226

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 14:20:46

US3592226

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:28
User entered '9 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 14:20:46

US3592226

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 14:20:46

US3592226

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:28
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 14:20:46

US3592226

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 14:21:15

US3592226

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:02
User entered 'l'	System	11 Nov 2020 14:21:15

US3592226

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 16:18:08

US3592226

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:43
User entered '14 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 16:18:08

US3592226

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Dec 2020 16:18:08

US3592226

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:43
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 16:18:08

US3592226

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 16:18:12

US3592226

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User entered 'l'	System	16 Dec 2020 16:18:12

US3592226

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:02:30
User entered 'Yes (Y)'	(D) (4), (b) (6)	08 Mar 2021 19:55:36

US3592226

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:02:30
User entered '12 Jan 2021'	(D) (4), (b) (6)	08 Mar 2021 19:55:36

US3592226

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:02:30
User entered 'Contact Made (CONTACT MADE)'	(D) (4), (b) (6)	08 Mar 2021 19:55:36

US3592226

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:02:30
User entered empty.	(D) (4), (b) (6)	08 Mar 2021 19:55:36

US3592226

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:03:19
User entered 'Yes (Y)'	(D) (4), (b) (6)	08 Mar 2021 19:55:41

US3592226

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User entered 'l'	System	08 Mar 2021 19:55:41

US3592226

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 04-Mar-2021(Accession No: 1F602238995)is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1). Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:03:16
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:05:04
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 04-Mar-2021(Accession No: 1F602238995)is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1). Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	08 Apr 2021 21:46:30
' answered with 'Confirm this has been entered in EDC' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 04-Mar-2021(Accession No: 1F602238995)is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1). Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	22 Mar 2021 12:28:05
' (Site from DM).		

US3592226

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:56:02

US3592226

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:53:09
User closed query 'Source documents successful contact on 15Feb2021. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:53:07
Query 'Source documents successful contact on 15Feb2021. Please review and update accordingly.' answered with 'updated date to when contact was successful' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	20 Apr 2021 19:18:07
User entered '15 Feb 2021' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	20 Apr 2021 19:17:52
User opened query 'Source documents successful contact on 15Feb2021. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:29:09
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 17:28:44
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:28:38
Query 'please verify as 15Feb2021 per source' canceled (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:28:35
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:06:49
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:05:04
User opened query 'please verify as 15Feb2021 per source' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:03:58
User entered '11 Feb 2021'	(b) (4), (b) (6)	08 Mar 2021 19:56:02

US3592226

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:05:04
User entered 'Contact Made (CONTACT MADE)'	(D) (4), (b) (6)	08 Mar 2021 19:56:02

US3592226

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:05:04
User entered empty.	(D) (4), (b) (6)	08 Mar 2021 19:56:02

US3592226

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:07:25
User entered 'Yes (Y)'	(D) (4), (b) (6)	08 Mar 2021 19:56:08

US3592226

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:10:58
User entered 'l'	System	08 Mar 2021 19:56:08

US3592226

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:11:18
User entered 'Yes (Y)'	(D) (4), (b) (6)	22 Mar 2021 16:39:45

US3592226

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:11:18
User entered '4 Mar 2021'	(D) (4), (b) (6)	22 Mar 2021 16:39:45

US3592226

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:11:18
User entered 'Clinic (Clinic)'	(D) (4), (b) (6)	22 Mar 2021 16:39:45

US3592226

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered 'VISIT4'	System	22 Mar 2021 16:39:45

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered '04 Mar 2021'	Diandra Henriques (b) (4) (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered '13:19'	Diandra Henriques (b) (4) (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered '04 Mar 2021 13:19'	System	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered '36.7' C	Diandra Henriques (b) (4) (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered 'Oral (Oral)'	Diandra Henriques (b) (4) (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered empty.	Diandra Henriques (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered '76'	Diandra Henriques (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered 'bpm'	System	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered '16'	Diandra Henriques (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered 'breaths/min'	System	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered '125'	Diandra Henriques (b) (4) (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered 'mmHg'	System	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:11:39
User entered '85'	Diandra Henriques (b) (4)	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered 'mmHg'	System	06 Apr 2021 20:48:52

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12

US3592226

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12

US3592226

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:12:18
User entered 'Yes (Y)'	(D) (4), (b) (6)	22 Mar 2021 16:40:09

US3592226

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:12:18
User entered '4 Mar 2021'	(D) (4), (b) (6)	22 Mar 2021 16:40:09

US3592226

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:12:25
User entered 'Yes (Y)'	(D) (4), (b) (6)	22 Mar 2021 16:40:22

US3592226

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:12:25
User entered '4 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:40:22

US3592226

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:12:25
User entered '13:49'	(D) (4), (b) (6)	22 Mar 2021 16:40:22

US3592226

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered '4 Mar 2021 13:49'	System	22 Mar 2021 16:40:22

US3592226

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:12:42
User entered 'Yes (Y)'	(D) (4), (b) (6)	22 Mar 2021 16:40:27

US3592226

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:12
User entered 'I'	System	22 Mar 2021 16:40:27

US3592226

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:09:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:38:27

US3592226

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:09:40
User entered '4 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:38:27

US3592226

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[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 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:09:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Mar 2021 16:38:27

US3592226

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User entered 'UNBLND_DECIDE'	System	22 Mar 2021 16:38:27

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User closed query 'Per CDM:Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:35:23
Query 'Per CDM:Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:40:27
User entered '4 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:40:15
User opened query 'Per CDM:Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 04:52:17
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

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 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:10:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	(D) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User entered '4 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:14
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User entered empty.	System	22 Mar 2021 16:38:55

US3592226

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User entered empty.	System	22 Mar 2021 16:38:55

US3592226

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:39:16

US3592226

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:30
User entered '4 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:39:16

US3592226

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:30
User entered '13:49'	(b) (4), (b) (6)	22 Mar 2021 16:39:16

US3592226

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User entered '4 Mar 2021 13:49'	System	22 Mar 2021 16:39:16

US3592226

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:39:27

US3592226

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:35
User entered '4 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:39:27

US3592226

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:35
User entered '13:35'	(b) (4), (b) (6)	22 Mar 2021 16:39:27

US3592226

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:10
User entered '4 Mar 2021 13:35'	System	22 Mar 2021 16:39:27

US3592226

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:20:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:50
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:34:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Oct 2020 14:27:46
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 21:39:48

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:42:49
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'no illness visit required since symptoms resolved before 48 hr mark and did not return.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:44:06
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (COUGH), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:57:45
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 14:29:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 14:29:39
Data point term sent to Coder	System	04 Oct 2020 14:28:33
User entered 'sore throat'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '28 Sep 2020'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 05:30:49
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".	(b) (4), (b) (6)	16 Dec 2020 16:20:33
' answered with 'stop date provided ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 16:20:08
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 23:48:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 16:20:08
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Oct 2020 14:28:52
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	04 Oct 2020 14:28:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Oct 2020 14:28:39
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'None (NONE)'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'l'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 16:20:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Oct 2020 14:28:52
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Oct 2020 14:28:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Oct 2020 14:28:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Oct 2020 14:28:39
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Oct 2020 14:28:32
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:20:38

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Oct 2020 14:28:32

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:43:38
Query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'no illness visit required since symptoms resolved before 48 hr mark and did not return' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:44:39
User opened query 'Per MM: the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:21:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 14:30:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 14:30:39
Data point term sent to Coder	System	04 Oct 2020 14:29:34
User entered 'cough'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '28 Sep 2020'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 05:31:27
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'stop date provided ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 16:21:09
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Dec 2020 16:20:56
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 23:48:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 16:21:05
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 16:21:05
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 16:21:05
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 16:21:05
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 16:20:56
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 16:20:56
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'None (NONE)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'l'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered '0'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	16 Dec 2020 16:20:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:35:58
User entered empty.	(b) (4), (b) (6)	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Oct 2020 14:29:23

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:38
User entered 'USA-US103-2021-mRNA-1273-P301000001'	System	15 Jan 2021 12:10:34
User entered 'New'	(b) (4), (b) (6)	15 Jan 2021 12:10:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Central nervous system and spinal infections, PT: Spinal cord abscess, LLT: Spinal cord abscess - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 23:39:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 23:39:59
Data point term sent to Coder	System	14 Jan 2021 23:39:28
User entered 'spinal cord abscess'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'No (N)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'No (N)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '17 Dec 2020'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:34:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:39:13
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 21:35:02
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Apr 2021 21:34:56
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Apr 2021 21:34:56
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Apr 2021 21:34:32
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:34:32
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:36:25
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1'	System	14 Jan 2021 23:38:34
	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:17:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '17 Dec 2020'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:37:19
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:09
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	14 Jan 2021 23:38:34
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:31
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:16:33
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered '0'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:39:18
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 21:35:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:34:56
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:36:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:15:46
User opened query 'Per DM CLR: SAE Narrative = VANCOMYCIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 00:45:49
User opened query 'Per DM CLR: SAE Narrative = REQUIRED EMERGENCY SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 00:45:43
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:38:02
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)	21 Jan 2021 15:37:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:36:54
User entered 'Subject reports he was having back pain on 17Dec2020 and went to the emergency room. Was found to have an abscess on his spinal cord that required emergency surgery due to the likelihood of it infiltrating the spinal fluid. Is currently still in the hospital being treated with Vancomycin for post-surgical infection. Release of records has been sent.'	(b) (4), (b) (6)	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	14 Jan 2021 23:38:34

US3592226

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 23:38:34

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:20:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:50
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:55:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:36:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:34:06

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
Query 'please update CM log pending receipt of hosp records' answered with 'will update once medical records have been received ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:12:59
User opened query 'please update CM log pending receipt of hosp records' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:20:34
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:36:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:37:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:37:40
Data point term sent to Coder	System	24 Sep 2020 21:36:59
User entered 'tylenol'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:36:30
User entered 'chronic back pain'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered '500'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:36:30
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered 'as needed (PRN)'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered 'un UNK 2010'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:36:30
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 21:36:30
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:35:58

US3592226

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:20:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:44:48
User signature succeeded.	Terry Poling (b) (4)	03 May 2021 19:54:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 21:30:45
User closed query 'please verify any procedures performed for SAE of spinal cord abscess' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 21:30:39
Query 'please verify any procedures performed for SAE of spinal cord abscess' answered with 'pending medical records ' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:13:20
User opened query 'please verify any procedures performed for SAE of spinal cord abscess' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:20:06
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 19:19:39
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 21:36:34
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 21:39:35

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:18
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'USA-US103-2021-MRNA-1273-P301000001'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:23:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Yes (Y)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:23:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Yes (Y)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:33
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Terry'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Poling'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered '1709 S Rock Rd'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Wichita'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'KS'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered '67207'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
User entered 'US'	System	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 13:06:14
User entered '1'	System	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:18
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'USA-US103-2021-MRNA-1273-P301000001'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Yes (Y)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Yes (Y)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:33
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Terry'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Poling'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered '1709 S Rock Rd'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Wichita'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'KS'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered '67207'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
User entered 'US'	System	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 13:06:14
User entered '1'	System	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
User entered '15/Jan/2021 07:10'	System	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:23:42
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:18
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'USA-US103-2021-MRNA-1273-P301000001'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:16
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Yes (Y)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Yes (Y)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:33
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'No (N)'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Terry'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Poling'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered '1709 S Rock Rd'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'Wichita'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered 'KS'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:10:48
User entered '67207'	System	15 Jan 2021 12:10:34

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
User entered 'US'	System	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 13:06:14
User entered '1'	System	15 Jan 2021 12:10:54

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
User entered '09/Apr/2021 06:06'	System	09 Apr 2021 13:06:14

US3592226

Folder: SAE USA-US103-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:35:49
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	15 Apr 2021 19:23:42
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:06:14