

US3592238 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:22:53

All time stamps listed in this document are displayed in GMT

US3592238

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Participant ID

US3592238

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

US3592238

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:31:13

Generated On: 10 Jun 2021 08:22:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ☒ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

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 16:31:13

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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 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	HYPEROPIA
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
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 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
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 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	HISTORY OF DEEP VEIN THROMBOSIS
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	PRE-DIABETIC
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	GOUT
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	RENAL AGENESIS (LEFT REMAINS)
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:31:13

Generated On: 10 Jun 2021 08:22:53

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 08:20
Height (xxx.x)	181.0 cm
Weight (xxx.x)	152.4 kg
BMI (xxx.x)	46.51873 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
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 16:31:13

Generated On: 10 Jun 2021 08:22:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 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 16:31:13

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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 16:31:13

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 144510

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 16:01:53

Generated On: 10 Jun 2021 08:22:53

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 16:01:53

Generated On: 10 Jun 2021 08:22:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	08:26 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 08:26
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 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 16:01:53

Generated On: 10 Jun 2021 08:22:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:55
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 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 16:01:53

Generated On: 10 Jun 2021 08:22:53

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 16:01:53

Generated On: 10 Jun 2021 08:22:53

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) 29 AUG 2020

What was the treatment time? (00:00-23:59) 10:21 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 10:21

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 16:01:53

Generated On: 10 Jun 2021 08:22:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	29 AUG 2020
Collection time (00:00-23:59)	09:38 (24 HR)
Collection date and time (derived)	29 AUG 2020 09:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:16	29 AUG 2020 09:16
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 29 AUG 2020 10:51

PC Open Date & Time 29 AUG 2020 10:41

PC Close Date & Time 29 AUG 2020 13:11

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 98.0 °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	29 AUG 2020 17:55
PC Open Date & Time	29 AUG 2020 14:06
PC Close Date & Time	30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

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

99.3 °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

30 AUG 2020 18:22

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

31 AUG 2020 17:58

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 16:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 18:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

29 AUG 2020 10:52

PC Open Date & Time

29 AUG 2020 10:41

PC Close Date & Time

29 AUG 2020 13:11

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 17:56

PC Open Date & Time

29 AUG 2020 14:06

PC Close Date & Time

30 AUG 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 18:23

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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

31 AUG 2020 17:59

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

01 SEP 2020 16:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

02 SEP 2020 19:00

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

03 SEP 2020 16:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

04 SEP 2020 16:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 10:52
PC Open Date & Time	29 AUG 2020 10:41
PC Close Date & Time	29 AUG 2020 13:11

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 17:56
PC Open Date & Time	29 AUG 2020 14:06
PC Close Date & Time	30 AUG 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 ☒

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	30 AUG 2020 18:24
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

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)

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	31 AUG 2020 17:59
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

53 of 1935

EAB) (1725)

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	01 SEP 2020 16:59
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

55 of 1935

EAB) (1725)

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	02 SEP 2020 19:00
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

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)

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	03 SEP 2020 16:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

59 of 1935

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US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	04 SEP 2020 16:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3592238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 09:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 10:12
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3592238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

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) 26 SEP 2020

What was the treatment time? (00:00-23:59) 09:39 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 09:39

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

US3592238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 SEP 2020

Collection time (00:00-23:59)

08:59 (24 HR)

Collection date and time (derived)

26 SEP 2020 08:59

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:00	26 SEP 2020 09:00
Nasopharyngeal Swab 2	No		

US3592238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

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

26 SEP 2020 09:59

PC Close Date & Time

26 SEP 2020 12:29

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.1 °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	26 SEP 2020 16:22
PC Open Date & Time	26 SEP 2020 13:24
PC Close Date & Time	27 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

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

98.1 °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

27 SEP 2020 18:27

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

28 SEP 2020 16:18

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

97.9 °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

29 SEP 2020 17:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

98.6 °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

30 SEP 2020 17:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 18:24

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 17:07

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 ☐

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

26 SEP 2020 09:59

PC Close Date & Time

26 SEP 2020 12:29

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 16:23

PC Open Date & Time

26 SEP 2020 13:24

PC Close Date & Time

27 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 ☐

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

2

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)**

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 18:29

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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

28 SEP 2020 16:19

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

29 SEP 2020 17:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

30 SEP 2020 17:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

01 OCT 2020 18:25

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

02 OCT 2020 17:08

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 09:59

PC Close Date & Time

26 SEP 2020 12:29

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 16:23
PC Open Date & Time	26 SEP 2020 13:24
PC Close Date & Time	27 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

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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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	27 SEP 2020 18:29
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	28 SEP 2020 16:20
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	29 SEP 2020 17:32
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	30 SEP 2020 17:04
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	01 OCT 2020 18:25
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

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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US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

Yes ☐	
PC Time stamp	02 OCT 2020 17:08
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3592238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:31:12

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:53

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 15:53
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	168 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

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.

US3592238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	16:50 (24 HR)
Collection date and time (derived)	26 OCT 2020 16:50

US3592238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:01:54

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 16:13:33

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

05 NOV 2020 18:15:10

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 NOV 2020 02:48:23

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 02:40:16
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 08:19:06
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 01:39:11
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

10 DEC 2020 17:35:34

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 16:25:54
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

24 DEC 2020 17:42:16

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

01 JAN 2021 09:07:19

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

07 JAN 2021 16:04:59

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 17:49:54

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

22 JAN 2021 04:28:28

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 19:41:53

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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	09 FEB 2021 15:49:53
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

15 FEB 2021 11:11:32

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

23 FEB 2021 21:43:28

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 16:13:03

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 15:56:25

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

17 MAR 2021 04:11:07

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	22 MAR 2021 14:12:44
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

30 MAR 2021 02:04:13

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	05 APR 2021 14:32:29
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 20:35:36
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 10:34:19

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

26 APR 2021 15:54:13

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

03 MAY 2021 20:19:26

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUN 2021 00:01
Patient Cloud Close Date & Time	25 JUN 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission	

Patient Cloud Open Date & Time	22 NOV 2021 00:01

Patient Cloud Close Date & Time	26 NOV 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

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04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

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22 APR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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29 APR 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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06 MAY 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

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13 MAY 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

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16 MAY 2022 00:01

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20 MAY 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

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27 MAY 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

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03 JUN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

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10 JUN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

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13 JUN 2022 00:01

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17 JUN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

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08 JUL 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

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15 JUL 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

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22 JUL 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

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25 JUL 2022 00:01

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29 JUL 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

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01 AUG 2022 00:01

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05 AUG 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

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08 AUG 2022 00:01

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12 AUG 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

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19 AUG 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

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26 AUG 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2022 00:01
Patient Cloud Close Date & Time	09 SEP 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

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12 SEP 2022 00:01

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16 SEP 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3592238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:22:53

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		01 MAR 2021 16:13:17

US3592238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:59:07

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:59:07

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3592238

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	16:03 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 16:03
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

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.

US3592238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	16:20 (24 HR)
Collection date and time (derived)	15 MAR 2021 16:20

US3592238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592238

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592238

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:22:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3592238

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	UNBLND_DECIDE

US3592238

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Date of updated informed consent (dd MMM yyyy) 8 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 8 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3592238

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	8 FEB 2021
Collection time (00:00-23:59)	15:40 (24 HR)
Collection date and time (derived)	8 FEB 2021 15:40

US3592238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	8 FEB 2021
Collection time (00:00 - 23:59)	15:44
Collection Date and Time (derived)	8 FEB 2021 15:44

US3592238

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:56:24

Generated On: 10 Jun 2021 08:22:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

AEID	USA-US103-2021-MRNA-1273-P30 1000008
Adverse event	HYPERGLYCEMIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	23 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	26 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	26 MAR 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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EAB) (1725)

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US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☒ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SUBJECT REPORTED DURING TC WITH RESEARCH ASSISTANT ON 05-APR-2021 AT 1503 THAT ON 23MAR2021 HE WAS EXPERIENCING BLURRED VISION AND DROVE HIMSELF TO THE EMERGENCY ROOM AT WESLEY MEDICAL CENTER.
Narrative	

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

HE WAS FOUND TO HAVE A
BLOOD GLUCOSE LEVEL OF 960
AND WAS ADMITTED TO THE
HOSPITAL. PER HIS REPORT HE
WAS DISCHARGED AFTER 4
DAYS ON INSULIN (LANTUS)
AND DIAGNOSED WITH
DIABETES. WILL HAVE
SUBJECT SIGN RECORD
RELEASE FOR MORE
INFORMATION FOLLOW UP
REPORT TO BE SUBMITTED
WHEN RECORDS RECEIVED.

4/15/2021 FU#1 MEDICAL
RECORDS RELEASE SENT BUT
RECORDS PENDING. SAE TERM
CHANGED FROM DIABETES TO
HYPERGLYCEMIA

4/21/21 FU#2 - UPDATED
OUTCOME AND END DATE.
RECORDS STILL PENDING.

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

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

AEID

Adverse event

DIABETES TYPE 2

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:53

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:22:53

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:53

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:22:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication NORVASC

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication ZOCOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 15:49:11

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication ALOPRIM

Prophylaxis Yes ☒
No ☐

Indication GOUT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:49:11

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication XARLTO

Prophylaxis Yes ☐
No ☒

Indication HISTORY OF DEEP VEIN
THROMBOSIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2006
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication BENICAR

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 15:49:11

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication TOPROL X

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:49:11

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication GLUCOPHAGE

Prophylaxis Yes ☐
No ☒

Indication PREDIABETIC

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:49:11

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	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

Name of Medication LANTUS SOLOSTAR

Prophylaxis Yes ☐
No ☒

Indication HYPERGLYCEMIA

Dose per administration 2

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:49:11

Generated On: 10 Jun 2021 08:22:53

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 15:56:25

Generated On: 10 Jun 2021 08:22:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:22:53

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

US3592238

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:22:53

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 ☐

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

SAEID	USA-US103-2021-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

SAEID	USA-US103-2021-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	07/APR/2021 15:31
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

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

SAEID	USA-US103-2021-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	16/APR/2021 09:49
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

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 09:42:25

Generated On: 10 Jun 2021 08:22:53

SAEID	USA-US103-2021-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 12:39
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

US3592238 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

(b)

US3592238

Form: Participant Creation

Generated On: 10 Jun 2021 08:22:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	01 Dec 2020 23:44:48
User entered 'US3592238'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:25:40

US3592238

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 19:06:47

US3592238

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:12
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:25:41

US3592238

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:54:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 19:06:47

US3592238

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'SCRN'	System	10 Sep 2020 19:06:47

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered (b) (6) 1959'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:25:41

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '61'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'YEARS'	System	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '61'	System	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered 'Male (M)'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered 'l'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:22:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:18
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 19:07:44

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:54:43
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Aug 2020'	System	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '2020'	System	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
Query 'Please clarify, there is no Protocol ICF for Amendment 3. Probably another Version for your site for Amendment 2.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:36:39
User opened query 'Please clarify, there is no Protocol ICF for Amendment 3. Probably another Version for your site for Amendment 2.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:55:46
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 20:54:43
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:30:54
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:43
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:43
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 15:26:07

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:54:43
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 13:25:41

US3592238

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:22:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'l'	System	29 Aug 2020 15:26:29

US3592238

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:55:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 15:26:29

US3592238

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:22:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:52:49

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 18:54:40
Data point term sent to Coder	System	29 Aug 2020 18:53:45
User entered 'Hyperopia'	(b) (4), (b) (6)	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 1965'	(b) (4), (b) (6)	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 18:53:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 18:53:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 18:53:13
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 18:53:04
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 1965'	System	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '1965'	System	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:53:04

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
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) (b) (4)	29 Aug 2020 18:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:54:40
Data point term sent to Coder	System	29 Aug 2020 18:53:45
User entered 'Hypertension'	(b) (4), (b) (6)	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 2000'	System	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '2000'	System	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:53:33

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 18:55:41
Data point term sent to Coder	System	29 Aug 2020 18:54:46
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 2000'	System	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '2000'	System	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:53:48

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
Data point term sent to Coder	System	29 Aug 2020 18:54:46
User entered 'History of Deep Vein Thrombosis'	(b) (4), (b) (6)	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 2006'	(b) (4), (b) (6)	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 2006'	System	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '2006'	System	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:54:12

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 18:55:41
Data point term sent to Coder	System	29 Aug 2020 18:54:48
User entered 'Pre-Diabetic'	(b) (4), (b) (6)	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 2017'	(b) (4), (b) (6)	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 2017'	System	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '2017'	System	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:54:39

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:13:52
Query 'Per DM CLR: Please specify the location Gout. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:32:39
User opened query 'Per DM CLR: Please specify the location Gout. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:13:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:58:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:58:42
Data point term sent to Coder	System	29 Aug 2020 18:57:51
User entered 'Gout'	(b) (4), (b) (6)	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 2000'	System	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '2000'	System	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:57:30

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Renal and urinary tract disorders congenital, HLT: Renal disorders congenital, PT: Renal aplasia, LLT: Unilateral renal agenesis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:26:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:26:47
Data point term sent to Coder	System	29 Aug 2020 18:59:53
User entered 'renal agenesis (left remains)'	(b) (4), (b) (6)	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 1996'	(b) (4), (b) (6)	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 1996'	System	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '1996'	System	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered empty.	System	29 Aug 2020 18:59:21

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
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) (b) (4)	29 Aug 2020 19:01:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 19:01:44
Data point term sent to Coder	System	29 Aug 2020 19:00:54
User entered 'Vasectomy'	(b) (4), (b) (6)	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 1996'	(b) (4), (b) (6)	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered 'UN UNK 1996'	(b) (4), (b) (6)	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:13:52
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 1996'	System	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '1996'	System	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'Jan 1996'	System	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '1996'	System	29 Aug 2020 19:00:27

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '08:20'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '29 Aug 2020 08:20'	System	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '181.0' cm	(b) (4), (b) (6)	29 Aug 2020 19:01:52
DataPoint set to visible.	System	29 Aug 2020 15:26:29

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '152.4' kg	(b) (4), (b) (6)	29 Aug 2020 19:01:52
DataPoint set to visible.	System	29 Aug 2020 15:26:29

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered '46.51873'	System	29 Aug 2020 19:01:52
DataPoint set to visible.	System	29 Aug 2020 15:26:29

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'kg/m2'	System	29 Aug 2020 19:01:52
DataPoint set to visible.	System	29 Aug 2020 15:26:29

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '98.1' F	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '73'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'bpm'	System	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '16'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'breaths/min'	System	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '140'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'mmHg'	System	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:14:55
User entered '95'	(b) (4), (b) (6)	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User entered 'mmHg'	System	29 Aug 2020 19:01:52

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28

US3592238

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28

US3592238

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:15:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:00:18
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:02:02

US3592238

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:15:02
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:00:18
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:02

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:09:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
User entered '0'	(b) (4) (u) (4), (u) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered 'l'	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
User entered '0'	(b) (4) (U) (4), (U) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:22:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:13:28
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:09:50

US3592238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 15:26:43

US3592238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:34
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 15:26:43

US3592238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Aug 2020 15:26:43

US3592238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'VISIT1'	System	29 Aug 2020 15:26:43

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:42
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 14:55:34

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:42
User entered '144510'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 14:55:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:42
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 14:55:34

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:42
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:11:06

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:42
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:11:06

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:11:06

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:42
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:11:06

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:42
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:11:06

US3592238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:42
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 20:33:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:35:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:35:43

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:24
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:15:15
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'deleted since not required' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 19:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:08:12
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:40:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Aug 2020 19:08:58
User entered '181' cm reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Aug 2020 19:02:18
User entered '181' (non-conformant).	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:08:12
User entered '152.4' kg reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:24
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:15:15
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'deleted since not required' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 19:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:08:12
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:40:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Aug 2020 19:08:58
User entered '181' cm reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Aug 2020 19:02:18
User entered '181' (non-conformant).	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:08:12
User entered '152.4' kg reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:08:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 19:08:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:02:18
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '08:26' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '29 Aug 2020 08:26'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'bpm'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'breaths/min'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '95' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:24
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:15:15
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'deleted since not required' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 19:08:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:08:12
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:40:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Aug 2020 19:08:58
User entered '181' cm reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Aug 2020 19:02:18
User entered '181' (non-conformant).	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:22:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 19:08:12
User entered '152.4' kg reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:24
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:08:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Aug 2020 19:08:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 19:02:18
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '10:55' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '29 Aug 2020 10:55'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:24
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '69' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'bpm'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'breaths/min'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '141' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:16:24
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 19:08:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:02:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	29 Aug 2020 19:08:58
User entered empty.	System	29 Aug 2020 19:02:18

US3592238

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:00:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:10:28

US3592238

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:56:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 17:00:30
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 19:10:28

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:42
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:27:40

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:42
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:42
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:42
User entered '10:21'	(b) (4), (b) (6)	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '29 Aug 2020 10:21'	System	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:16:42
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:16:42
User entered 'ONCE'	System	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 15:27:40

US3592238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:11:23

US3592238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:53
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 19:11:23

US3592238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:53
User entered '09:38'	(b) (4), (b) (6)	29 Aug 2020 19:11:23

US3592238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '29 Aug 2020 09:38'	System	29 Aug 2020 19:11:23

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:58
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:58
User entered '09:16'	(b) (4), (b) (6)	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '29 Aug 2020 09:16'	System	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:58
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:56:58
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered empty.	System	29 Aug 2020 19:11:41

US3592238

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 20:57:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:12:03

US3592238

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	29 Aug 2020 19:12:03

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:50:58', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd51fdd0d-7ba4-40c4-aac1-55376f370844'	System	29 Aug 2020 15:51:28
User entered 'Yes (Y)'	System	29 Aug 2020 15:51:28

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:51:09', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd51fdd0d-7ba4-40c4-aac1-55376f370844' User entered '97.2'	System	29 Aug 2020 15:51:28
	System	29 Aug 2020 15:51:28

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:51:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd51fdd0d-7ba4-40c4-aac1-55376f370844'	System	29 Aug 2020 15:51:28
User entered 'No (N)'	System	29 Aug 2020 15:51:28

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:51:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd51fdd0d-7ba4-40c4-aac1-55376f370844'	System	29 Aug 2020 15:51:28
User entered '29 Aug 2020 10:51'	System	29 Aug 2020 15:51:28

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 10:41'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 13:11'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:55:17', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '587da064-45aa-4759-8187-26a5fdc89121'	System	29 Aug 2020 22:55:42
User entered 'Yes (Y)'	System	29 Aug 2020 22:55:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:55:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '587da064-45aa-4759-8187-26a5fdc89121' User entered '98.0'	System	29 Aug 2020 22:55:42
	System	29 Aug 2020 22:55:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:55:31', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '587da064-45aa-4759-8187-26a5fdc89121'	System	29 Aug 2020 22:55:42
User entered 'No (N)'	System	29 Aug 2020 22:55:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:55:37', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '587da064-45aa-4759-8187-26a5fdc89121'	System	29 Aug 2020 22:55:42
User entered '29 Aug 2020 17:55'	System	29 Aug 2020 22:55:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 14:06'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 2'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:22:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'e8fee48e-ce84-4661-bc4b-93b616205a00'	System	30 Aug 2020 23:22:47
User entered 'Yes (Y)'	System	30 Aug 2020 23:22:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:22:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'e8fee48e-ce84-4661-bc4b-93b616205a00' User entered '99.3'	System	30 Aug 2020 23:22:47
	System	30 Aug 2020 23:22:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:22:39', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'e8fee48e-ce84-4661-bc4b-93b616205a00'	System	30 Aug 2020 23:22:47
User entered 'No (N)'	System	30 Aug 2020 23:22:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:22:43', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'e8fee48e-ce84-4661-bc4b-93b616205a00' User entered '30 Aug 2020 18:22'	System	30 Aug 2020 23:22:47
	System	30 Aug 2020 23:22:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 3'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:58:28', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '73819058-9f3e-4b70-9d9d-e7ee49d7ad83'	System	31 Aug 2020 22:58:47
User entered 'Yes (Y)'	System	31 Aug 2020 22:58:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:58:35', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '73819058-9f3e-4b70-9d9d-e7ee49d7ad83' User entered '98.3'	System	31 Aug 2020 22:58:47
	System	31 Aug 2020 22:58:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:58:39', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '73819058-9f3e-4b70-9d9d-e7ee49d7ad83'	System	31 Aug 2020 22:58:47
User entered 'No (N)'	System	31 Aug 2020 22:58:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:58:44', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '73819058-9f3e-4b70-9d9d-e7ee49d7ad83'	System	31 Aug 2020 22:58:47
User entered '31 Aug 2020 17:58'	System	31 Aug 2020 22:58:47

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 4'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:57:37', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '23ad63ad-2d66-4ee4-86d9-34c9a8e42ca0'	System	01 Sep 2020 21:58:16
User entered 'Yes (Y)'	System	01 Sep 2020 21:58:16

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:04', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '23ad63ad-2d66-4ee4-86d9-34c9a8e42ca0' User entered '98.8'	System	01 Sep 2020 21:58:16
	System	01 Sep 2020 21:58:16

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:09', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '23ad63ad-2d66-4ee4-86d9-34c9a8e42ca0'	System	01 Sep 2020 21:58:16
User entered 'No (N)'	System	01 Sep 2020 21:58:16

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:13', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '23ad63ad-2d66-4ee4-86d9-34c9a8e42ca0' User entered '01 Sep 2020 16:58'	System	01 Sep 2020 21:58:16
	System	01 Sep 2020 21:58:16

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 5'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T18:59:33', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'af05c9f8-7a22-43d9-bb8f-bd3a7806843d' User entered 'Yes (Y)'	System	02 Sep 2020 23:59:51
	System	02 Sep 2020 23:59:51

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T18:59:39', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'af05c9f8-7a22-43d9-bb8f-bd3a7806843d' User entered '99.1'	System	02 Sep 2020 23:59:51
	System	02 Sep 2020 23:59:51

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T18:59:44', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'af05c9f8-7a22-43d9-bb8f-bd3a7806843d'	System	02 Sep 2020 23:59:51
User entered 'No (N)'	System	02 Sep 2020 23:59:51

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T18:59:49', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'af05c9f8-7a22-43d9-bb8f-bd3a7806843d' User entered '02 Sep 2020 18:59'	System	02 Sep 2020 23:59:51
	System	02 Sep 2020 23:59:51

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 6'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:03:59', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c044d294-1292-468b-b8e9-0d9b6ab7fbbd' User entered 'Yes (Y)'	System	03 Sep 2020 21:04:17
	System	03 Sep 2020 21:04:17

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:05', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c044d294-1292-468b-b8e9-0d9b6ab7fbbd' User entered '98.8'	System	03 Sep 2020 21:04:17
	System	03 Sep 2020 21:04:17

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:10', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c044d294-1292-468b-b8e9-0d9b6ab7fbbd'	System	03 Sep 2020 21:04:17
User entered 'No (N)'	System	03 Sep 2020 21:04:17

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:14', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c044d294-1292-468b-b8e9-0d9b6ab7fbbd' User entered '03 Sep 2020 16:04'	System	03 Sep 2020 21:04:17
	System	03 Sep 2020 21:04:17

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 7'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:01:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8b6f515d-b3dc-47d6-a80d-647422469c0c' User entered 'Yes (Y)'	System	04 Sep 2020 21:01:42
	System	04 Sep 2020 21:01:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:01:23', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8b6f515d-b3dc-47d6-a80d-647422469c0c' User entered '98.2'	System	04 Sep 2020 21:01:42
	System	04 Sep 2020 21:01:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:01:36', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8b6f515d-b3dc-47d6-a80d-647422469c0c' User entered 'No (N)'	System	04 Sep 2020 21:01:42
	System	04 Sep 2020 21:01:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:01:40', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8b6f515d-b3dc-47d6-a80d-647422469c0c' User entered '04 Sep 2020 16:01'	System	04 Sep 2020 21:01:42
	System	04 Sep 2020 21:01:42

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:51:42', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9eaab654-5b67-4fff-b5ee-792a8209c512'	System	29 Aug 2020 15:52:07
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 15:52:07

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:51:46', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9eaab654-5b67-4fff-b5ee-792a8209c512'	System	29 Aug 2020 15:52:07
User entered 'No (N)'	System	29 Aug 2020 15:52:07

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:51:51', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9eaab654-5b67-4fff-b5ee-792a8209c512'	System	29 Aug 2020 15:52:07
User entered 'No (N)'	System	29 Aug 2020 15:52:07

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:51:58', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9eaab654-5b67-4fff-b5ee-792a8209c512'	System	29 Aug 2020 15:52:07
User entered 'None (1)'	System	29 Aug 2020 15:52:07

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:05', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9eaab654-5b67-4fff-b5ee-792a8209c512'	System	29 Aug 2020 15:52:07
User entered '29 Aug 2020 10:52'	System	29 Aug 2020 15:52:07

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 10:41'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 13:11'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:55:52', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd87e5ddb-b640-4820-860b-8b3577370913'	System	29 Aug 2020 22:56:17
User entered 'None (1)'	System	29 Aug 2020 22:56:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:55:58', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd87e5ddb-b640-4820-860b-8b3577370913'	System	29 Aug 2020 22:56:17
User entered 'No (N)'	System	29 Aug 2020 22:56:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:02', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd87e5ddb-b640-4820-860b-8b3577370913'	System	29 Aug 2020 22:56:17
User entered 'No (N)'	System	29 Aug 2020 22:56:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd87e5ddb-b640-4820-860b-8b3577370913'	System	29 Aug 2020 22:56:17
User entered 'None (1)'	System	29 Aug 2020 22:56:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:11', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd87e5ddb-b640-4820-860b-8b3577370913'	System	29 Aug 2020 22:56:17
User entered '29 Aug 2020 17:56'	System	29 Aug 2020 22:56:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 14:06'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 2'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:23:05', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '14a24ab1-9914-454c-be00-9adecddb4566'	System	30 Aug 2020 23:23:58
User entered 'None (1)'	System	30 Aug 2020 23:23:58

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:23:09', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '14a24ab1-9914-454c-be00-9adecddb4566'	System	30 Aug 2020 23:23:58
User entered 'No (N)'	System	30 Aug 2020 23:23:58

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:23:19', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '14a24ab1-9914-454c-be00-9adecddb4566'	System	30 Aug 2020 23:23:58
User entered 'Yes (Y)'	System	30 Aug 2020 23:23:58

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:23:44', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '14a24ab1-9914-454c-be00-9adecddb4566' User entered '2'	System	30 Aug 2020 23:23:58
	System	30 Aug 2020 23:23:58

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:23:48', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '14a24ab1-9914-454c-be00-9adecddb4566'	System	30 Aug 2020 23:23:58
User entered 'None (1)'	System	30 Aug 2020 23:23:58

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:23:56', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '14a24ab1-9914-454c-be00-9adecddb4566' User entered '30 Aug 2020 18:23'	System	30 Aug 2020 23:23:58
	System	30 Aug 2020 23:23:58

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 3'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:58:51', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '84113ea1-341a-4f47-9809-d36dd0d65bb0' User entered 'None (1)'	System	31 Aug 2020 22:59:14
	System	31 Aug 2020 22:59:14

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:58:55', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '84113ea1-341a-4f47-9809-d36dd0d65bb0' User entered 'No (N)'	System	31 Aug 2020 22:59:14
	System	31 Aug 2020 22:59:14

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:58:59', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '84113ea1-341a-4f47-9809-d36dd0d65bb0' User entered 'No (N)'	System	31 Aug 2020 22:59:14
	System	31 Aug 2020 22:59:14

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:05', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '84113ea1-341a-4f47-9809-d36dd0d65bb0' User entered 'None (1)'	System	31 Aug 2020 22:59:14
	System	31 Aug 2020 22:59:14

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:09', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '84113ea1-341a-4f47-9809-d36dd0d65bb0' User entered '31 Aug 2020 17:59'	System	31 Aug 2020 22:59:14
	System	31 Aug 2020 22:59:14

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 4'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d57ecd6-44e9-496d-9a0f-d448b629fec7' User entered 'None (1)'	System	01 Sep 2020 21:58:50
	System	01 Sep 2020 21:58:50

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d57ecd6-44e9-496d-9a0f-d448b629fec7' User entered 'No (N)'	System	01 Sep 2020 21:58:50
	System	01 Sep 2020 21:58:50

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:28', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d57ecd6-44e9-496d-9a0f-d448b629fec7' User entered 'No (N)'	System	01 Sep 2020 21:58:50
	System	01 Sep 2020 21:58:50

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d57ecd6-44e9-496d-9a0f-d448b629fec7' User entered 'None (1)'	System	01 Sep 2020 21:58:50
	System	01 Sep 2020 21:58:50

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:46', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d57ecd6-44e9-496d-9a0f-d448b629fec7' User entered '01 Sep 2020 16:58'	System	01 Sep 2020 21:58:50
	System	01 Sep 2020 21:58:50

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 5'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T18:59:55', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '35a38216-ccbb-4f29-8f54-897261b0136e' User entered 'None (1)'	System	03 Sep 2020 00:00:17
	System	03 Sep 2020 00:00:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:03', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '35a38216-ccbb-4f29-8f54-897261b0136e' User entered 'No (N)'	System	03 Sep 2020 00:00:17
	System	03 Sep 2020 00:00:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '35a38216-ccbb-4f29-8f54-897261b0136e' User entered 'No (N)'	System	03 Sep 2020 00:00:17
	System	03 Sep 2020 00:00:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:11', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '35a38216-ccbb-4f29-8f54-897261b0136e' User entered 'None (1)'	System	03 Sep 2020 00:00:17
	System	03 Sep 2020 00:00:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:15', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '35a38216-ccbb-4f29-8f54-897261b0136e' User entered '02 Sep 2020 19:00'	System	03 Sep 2020 00:00:17
	System	03 Sep 2020 00:00:17

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 6'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fa741bdf-1189-4b1a-89f8-bf5ad074fc55'	System	03 Sep 2020 21:04:39
User entered 'None (1)'	System	03 Sep 2020 21:04:39

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:23', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fa741bdf-1189-4b1a-89f8-bf5ad074fc55'	System	03 Sep 2020 21:04:39
User entered 'No (N)'	System	03 Sep 2020 21:04:39

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fa741bdf-1189-4b1a-89f8-bf5ad074fc55'	System	03 Sep 2020 21:04:39
User entered 'No (N)'	System	03 Sep 2020 21:04:39

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:33', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fa741bdf-1189-4b1a-89f8-bf5ad074fc55'	System	03 Sep 2020 21:04:39
User entered 'None (1)'	System	03 Sep 2020 21:04:39

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:36', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fa741bdf-1189-4b1a-89f8-bf5ad074fc55'	System	03 Sep 2020 21:04:39
User entered '03 Sep 2020 16:04'	System	03 Sep 2020 21:04:39

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 7'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:01:46', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'a47e4a5a-61a3-4930-ad90-81149df541ed'	System	04 Sep 2020 21:02:15
User entered 'None (1)'	System	04 Sep 2020 21:02:15

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:01:50', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'a47e4a5a-61a3-4930-ad90-81149df541ed' User entered 'No (N)'	System	04 Sep 2020 21:02:15
	System	04 Sep 2020 21:02:15

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'a47e4a5a-61a3-4930-ad90-81149df541ed' User entered 'No (N)'	System	04 Sep 2020 21:02:15
	System	04 Sep 2020 21:02:15

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:05', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'a47e4a5a-61a3-4930-ad90-81149df541ed'	System	04 Sep 2020 21:02:15
User entered 'None (1)'	System	04 Sep 2020 21:02:15

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:08', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'a47e4a5a-61a3-4930-ad90-81149df541ed' User entered '04 Sep 2020 16:02'	System	04 Sep 2020 21:02:15
	System	04 Sep 2020 21:02:15

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:13', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered 'None (0)'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:23', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered 'None (0)'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered 'None (0)'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:35', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered 'None (0)'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:40', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered 'None (0)'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:43', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered 'None (0)'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:49', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered 'No (N)'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T10:52:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f6dd51fd-a566-4c8e-a4b6-903c593d68ff' User entered '29 Aug 2020 10:52'	System	29 Aug 2020 15:52:54
	System	29 Aug 2020 15:52:54

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 10:41'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 13:11'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:17', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571' User entered 'None (0)'	System	29 Aug 2020 22:56:51
	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:22', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571' User entered 'None (0)'	System	29 Aug 2020 22:56:51
	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571' User entered 'None (0)'	System	29 Aug 2020 22:56:51
	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

JOINT ACES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:28', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571' User entered 'None (0)'	System	29 Aug 2020 22:56:51
	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:31', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571' User entered 'None (0)'	System	29 Aug 2020 22:56:51
	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571' User entered 'None (0)'	System	29 Aug 2020 22:56:51
	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:45', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571'	System	29 Aug 2020 22:56:51
User entered 'No (N)'	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-29T17:56:50', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2faac71f-6c9c-4821-8adb-231465124571' User entered '29 Aug 2020 17:56'	System	29 Aug 2020 22:56:51
	System	29 Aug 2020 22:56:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Aug 2020 14:06'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 2'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:02', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered 'None (0)'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered 'None (0)'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:11', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered 'None (0)'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:14', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered 'None (0)'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:17', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered 'None (0)'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered 'None (0)'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:30', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered 'No (N)'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-30T18:24:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '091b3733-5415-418e-84f0-6354de3937eb' User entered '30 Aug 2020 18:24'	System	30 Aug 2020 23:24:37
	System	30 Aug 2020 23:24:37

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 3'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:14', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered 'None (0)'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:17', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered 'None (0)'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:21', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered 'None (0)'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered 'None (0)'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered 'None (0)'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:30', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered 'None (0)'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:40', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered 'No (N)'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-08-31T17:59:44', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cfbea404-9d0b-4fa9-8d22-01216af4a09f' User entered '31 Aug 2020 17:59'	System	31 Aug 2020 22:59:46
	System	31 Aug 2020 22:59:46

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 4'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:52', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered 'None (0)'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:55', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered 'None (0)'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:58:58', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered 'None (0)'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:59:02', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered 'None (0)'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:59:05', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered 'None (0)'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:59:08', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered 'None (0)'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:59:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered 'No (N)'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-01T16:59:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3cee5e3e-1a95-4982-881b-ace8d02a789a' User entered '01 Sep 2020 16:59'	System	01 Sep 2020 21:59:22
	System	01 Sep 2020 21:59:22

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 5'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:21', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70' User entered 'None (0)'	System	03 Sep 2020 00:00:51
	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70'	System	03 Sep 2020 00:00:51
User entered 'None (0)'	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:29', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70' User entered 'None (0)'	System	03 Sep 2020 00:00:51
	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:33', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70' User entered 'None (0)'	System	03 Sep 2020 00:00:51
	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:36', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70' User entered 'None (0)'	System	03 Sep 2020 00:00:51
	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:39', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70' User entered 'None (0)'	System	03 Sep 2020 00:00:51
	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:45', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70' User entered 'No (N)'	System	03 Sep 2020 00:00:51
	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-02T19:00:48', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '999e4131-249f-4cb1-a133-37765f709c70' User entered '02 Sep 2020 19:00'	System	03 Sep 2020 00:00:51
	System	03 Sep 2020 00:00:51

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 6'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:41', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279' User entered 'None (0)'	System	03 Sep 2020 21:05:09
	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:44', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279' User entered 'None (0)'	System	03 Sep 2020 21:05:09
	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:47', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279' User entered 'None (0)'	System	03 Sep 2020 21:05:09
	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:50', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279' User entered 'None (0)'	System	03 Sep 2020 21:05:09
	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279' User entered 'None (0)'	System	03 Sep 2020 21:05:09
	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:04:56', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279' User entered 'None (0)'	System	03 Sep 2020 21:05:09
	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:05:02', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279' User entered 'No (N)'	System	03 Sep 2020 21:05:09
	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-03T16:05:06', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '6bcef84b-07f6-403f-b0a7-519808b7e279'	System	03 Sep 2020 21:05:09
User entered '03 Sep 2020 16:05'	System	03 Sep 2020 21:05:09

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 7'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:14', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered 'None (0)'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:17', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered 'None (0)'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:21', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered 'None (0)'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered 'None (0)'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:30', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered 'None (0)'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:33', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered 'None (0)'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:37', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered 'No (N)'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-04T16:02:40', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'cd87d098-0c42-452c-b43b-82c20a2e8056' User entered '04 Sep 2020 16:02'	System	04 Sep 2020 21:02:43
	System	04 Sep 2020 21:02:43

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 15:27:40

US3592238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:17:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 14:39:54

US3592238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:17:18
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 14:39:54

US3592238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:17:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Sep 2020 14:39:54

US3592238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:17:18
User entered empty.	(b) (4), (b) (6)	07 Sep 2020 14:39:54

US3592238

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:57:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 14:39:58

US3592238

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	07 Sep 2020 14:39:58

US3592238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:17:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:59:54

US3592238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:17:43
User entered '13 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:59:54

US3592238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:17:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 16:59:54

US3592238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:17:43
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:59:54

US3592238

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:57:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:00:00

US3592238

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	14 Sep 2020 17:00:00

US3592238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:18:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Sep 2020 16:04:32

US3592238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:18:31
User entered '19 Sep 2020'	(b) (4), (b) (6)	20 Sep 2020 16:04:32

US3592238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:18:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Sep 2020 16:04:32

US3592238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:18:31
User entered empty.	(b) (4), (b) (6)	20 Sep 2020 16:04:32

US3592238

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 20:57:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Sep 2020 16:04:55

US3592238

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	20 Sep 2020 16:04:55

US3592238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:39:47

US3592238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:05:37
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:39:47

US3592238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Sep 2020 16:39:47

US3592238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'VISIT2'	System	26 Sep 2020 16:39:47

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '09:10'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '26 Sep 2020 09:10'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '97.9' F	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:25
User entered '75'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'bpm'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'breaths/min'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:25
User entered '153'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '94'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '10:12'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '26 Sep 2020 10:12'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '97.8' F	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:25
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:25
User entered '66'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'bpm'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'breaths/min'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '149'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:25
User entered '97'	(b) (4), (b) (6)	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	26 Sep 2020 16:41:39

US3592238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:41:58

US3592238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:31
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:41:58

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:45
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:45
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:20:45
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:45
User entered '09:39'	(b) (4), (b) (6)	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '26 Sep 2020 09:39'	System	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:20:45
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:20:45
User entered 'ONCE'	System	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:22:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 14:43:24

US3592238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:42:28

US3592238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:42
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:42:28

US3592238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:42
User entered '08:59'	(b) (4), (b) (6)	26 Sep 2020 16:42:28

US3592238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '26 Sep 2020 08:59'	System	26 Sep 2020 16:42:28

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:46
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:46
User entered '09:00'	(b) (4), (b) (6)	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '26 Sep 2020 09:00'	System	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:46
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:46
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered empty.	System	26 Sep 2020 16:42:49

US3592238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	29 Oct 2020 21:05:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:43:00

US3592238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'I'	System	26 Sep 2020 16:43:00

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 09:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 12:29'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:22:08', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9f0206ad-6934-4029-9324-6c61de276527'	System	26 Sep 2020 21:22:32
User entered 'Yes (Y)'	System	26 Sep 2020 21:22:32

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:22:18', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9f0206ad-6934-4029-9324-6c61de276527' User entered '97.1'	System	26 Sep 2020 21:22:32
	System	26 Sep 2020 21:22:32

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:22:22', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9f0206ad-6934-4029-9324-6c61de276527'	System	26 Sep 2020 21:22:32
User entered 'No (N)'	System	26 Sep 2020 21:22:32

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:22:29', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9f0206ad-6934-4029-9324-6c61de276527' User entered '26 Sep 2020 16:22'	System	26 Sep 2020 21:22:32
	System	26 Sep 2020 21:22:32

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 13:24'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 2'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:27:11', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '675c7216-0e54-499b-b40d-029a750ed2e5' User entered 'Yes (Y)'	System	27 Sep 2020 23:27:31
	System	27 Sep 2020 23:27:31

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:27:18', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '675c7216-0e54-499b-b40d-029a750ed2e5' User entered '98.1'	System	27 Sep 2020 23:27:31
	System	27 Sep 2020 23:27:31

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:27:22', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '675c7216-0e54-499b-b40d-029a750ed2e5' User entered 'No (N)'	System	27 Sep 2020 23:27:31
	System	27 Sep 2020 23:27:31

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:27:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '675c7216-0e54-499b-b40d-029a750ed2e5' User entered '27 Sep 2020 18:27'	System	27 Sep 2020 23:27:31
	System	27 Sep 2020 23:27:31

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 3'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:18:43', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b93e3bd0-93de-4b17-bb20-b409c544e0f5' User entered 'Yes (Y)'	System	28 Sep 2020 21:19:03
	System	28 Sep 2020 21:19:03

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:18:49', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b93e3bd0-93de-4b17-bb20-b409c544e0f5' User entered '98.1'	System	28 Sep 2020 21:19:03
	System	28 Sep 2020 21:19:03

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:18:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b93e3bd0-93de-4b17-bb20-b409c544e0f5'	System	28 Sep 2020 21:19:03
User entered 'No (N)'	System	28 Sep 2020 21:19:03

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:18:57', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b93e3bd0-93de-4b17-bb20-b409c544e0f5' User entered '28 Sep 2020 16:18'	System	28 Sep 2020 21:19:03
	System	28 Sep 2020 21:19:03

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 4'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:31:43', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '0fdeef4b-d2b8-4765-a1d9-998a38e02605'	System	29 Sep 2020 22:32:04
User entered 'Yes (Y)'	System	29 Sep 2020 22:32:04

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:31:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '0fdeef4b-d2b8-4765-a1d9-998a38e02605' User entered '97.9'	System	29 Sep 2020 22:32:04
	System	29 Sep 2020 22:32:04

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:31:58', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '0fdeef4b-d2b8-4765-a1d9-998a38e02605'	System	29 Sep 2020 22:32:04
User entered 'No (N)'	System	29 Sep 2020 22:32:04

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:01', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '0fdeef4b-d2b8-4765-a1d9-998a38e02605' User entered '29 Sep 2020 17:32'	System	29 Sep 2020 22:32:04
	System	29 Sep 2020 22:32:04

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 5'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:03:47', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9d14d10d-6e70-44d5-9974-a7474b5a5400'	System	30 Sep 2020 22:04:09
User entered 'Yes (Y)'	System	30 Sep 2020 22:04:09

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:03:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9d14d10d-6e70-44d5-9974-a7474b5a5400' User entered '98.6'	System	30 Sep 2020 22:04:09
	System	30 Sep 2020 22:04:09

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:03:59', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9d14d10d-6e70-44d5-9974-a7474b5a5400'	System	30 Sep 2020 22:04:09
User entered 'No (N)'	System	30 Sep 2020 22:04:09

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:03', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9d14d10d-6e70-44d5-9974-a7474b5a5400' User entered '30 Sep 2020 17:04'	System	30 Sep 2020 22:04:09
	System	30 Sep 2020 22:04:09

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 6'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:24:15', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2e35954a-62b8-411c-8bd1-a8c91adfd418' User entered 'Yes (Y)'	System	01 Oct 2020 23:24:43
	System	01 Oct 2020 23:24:43

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:24:32', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2e35954a-62b8-411c-8bd1-a8c91adfd418' User entered '98.5'	System	01 Oct 2020 23:24:43
	System	01 Oct 2020 23:24:43

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:24:37', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2e35954a-62b8-411c-8bd1-a8c91adfd418'	System	01 Oct 2020 23:24:43
User entered 'No (N)'	System	01 Oct 2020 23:24:43

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:24:40', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2e35954a-62b8-411c-8bd1-a8c91adfd418' User entered '01 Oct 2020 18:24'	System	01 Oct 2020 23:24:43
	System	01 Oct 2020 23:24:43

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 7'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:07:23', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '80c9b1ca-16ac-491e-84a3-e1680d96233e' User entered 'Yes (Y)'	System	02 Oct 2020 22:07:41
	System	02 Oct 2020 22:07:41

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:07:29', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '80c9b1ca-16ac-491e-84a3-e1680d96233e' User entered '98.1'	System	02 Oct 2020 22:07:41
	System	02 Oct 2020 22:07:41

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:07:35', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '80c9b1ca-16ac-491e-84a3-e1680d96233e'	System	02 Oct 2020 22:07:41
User entered 'No (N)'	System	02 Oct 2020 22:07:41

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:07:39', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '80c9b1ca-16ac-491e-84a3-e1680d96233e' User entered '02 Oct 2020 17:07'	System	02 Oct 2020 22:07:41
	System	02 Oct 2020 22:07:41

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 09:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 12:29'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:22:42', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9b483beb-ea72-4892-bfa7-1cfb78e3021f' User entered 'None (1)'	System	26 Sep 2020 21:23:16
	System	26 Sep 2020 21:23:16

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:22:58', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9b483beb-ea72-4892-bfa7-1cfb78e3021f' User entered 'No (N)'	System	26 Sep 2020 21:23:16
	System	26 Sep 2020 21:23:16

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:02', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9b483beb-ea72-4892-bfa7-1cfb78e3021f' User entered 'No (N)'	System	26 Sep 2020 21:23:16
	System	26 Sep 2020 21:23:16

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9b483beb-ea72-4892-bfa7-1cfb78e3021f' User entered 'None (1)'	System	26 Sep 2020 21:23:16
	System	26 Sep 2020 21:23:16

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:12', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9b483beb-ea72-4892-bfa7-1cfb78e3021f' User entered '26 Sep 2020 16:23'	System	26 Sep 2020 21:23:16
	System	26 Sep 2020 21:23:16

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 13:24'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 2'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:27:41', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ce3d9dd5-4c42-4d45-841d-eeeb11554ff8'	System	27 Sep 2020 23:29:09
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 23:29:09

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:28:15', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ce3d9dd5-4c42-4d45-841d-eeeb11554ff8'	System	27 Sep 2020 23:29:09
User entered 'Yes (Y)'	System	27 Sep 2020 23:29:09

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:28:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ce3d9dd5-4c42-4d45-841d-eeeb11554ff8' User entered '2'	System	27 Sep 2020 23:29:09
	System	27 Sep 2020 23:29:09

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:28:36', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ce3d9dd5-4c42-4d45-841d-eeeb11554ff8'	System	27 Sep 2020 23:29:09
User entered 'Yes (Y)'	System	27 Sep 2020 23:29:09

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:28:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ce3d9dd5-4c42-4d45-841d-eeeb11554ff8' User entered '4'	System	27 Sep 2020 23:29:09
	System	27 Sep 2020 23:29:09

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:28:58', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ce3d9dd5-4c42-4d45-841d-eeeb11554ff8'	System	27 Sep 2020 23:29:09
User entered 'None (1)'	System	27 Sep 2020 23:29:09

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:03', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ce3d9dd5-4c42-4d45-841d-eeeb11554ff8'	System	27 Sep 2020 23:29:09
User entered '27 Sep 2020 18:29'	System	27 Sep 2020 23:29:09

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 3'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b4fca388-e732-46d9-bc65-98de3d59f713'	System	28 Sep 2020 21:19:27
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 21:19:27

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:12', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b4fca388-e732-46d9-bc65-98de3d59f713'	System	28 Sep 2020 21:19:27
User entered 'No (N)'	System	28 Sep 2020 21:19:27

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b4fca388-e732-46d9-bc65-98de3d59f713'	System	28 Sep 2020 21:19:27
User entered 'No (N)'	System	28 Sep 2020 21:19:27

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:21', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b4fca388-e732-46d9-bc65-98de3d59f713'	System	28 Sep 2020 21:19:27
User entered 'None (1)'	System	28 Sep 2020 21:19:27

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b4fca388-e732-46d9-bc65-98de3d59f713' User entered '28 Sep 2020 16:19'	System	28 Sep 2020 21:19:27
	System	28 Sep 2020 21:19:27

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 4'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:10', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f35399c9-6835-4f5b-aa35-34d186dda0b7'	System	29 Sep 2020 22:32:30
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 22:32:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:14', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f35399c9-6835-4f5b-aa35-34d186dda0b7'	System	29 Sep 2020 22:32:30
User entered 'No (N)'	System	29 Sep 2020 22:32:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:17', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f35399c9-6835-4f5b-aa35-34d186dda0b7' User entered 'No (N)'	System	29 Sep 2020 22:32:30
	System	29 Sep 2020 22:32:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:21', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f35399c9-6835-4f5b-aa35-34d186dda0b7'	System	29 Sep 2020 22:32:30
User entered 'None (1)'	System	29 Sep 2020 22:32:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'f35399c9-6835-4f5b-aa35-34d186dda0b7' User entered '29 Sep 2020 17:32'	System	29 Sep 2020 22:32:30
	System	29 Sep 2020 22:32:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 5'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:09', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '34016d18-7e37-41c6-a968-7d7eff3c5204'	System	30 Sep 2020 22:04:30
User entered 'None (1)'	System	30 Sep 2020 22:04:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '34016d18-7e37-41c6-a968-7d7eff3c5204' User entered 'No (N)'	System	30 Sep 2020 22:04:30
	System	30 Sep 2020 22:04:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:21', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '34016d18-7e37-41c6-a968-7d7eff3c5204' User entered 'No (N)'	System	30 Sep 2020 22:04:30
	System	30 Sep 2020 22:04:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '34016d18-7e37-41c6-a968-7d7eff3c5204'	System	30 Sep 2020 22:04:30
User entered 'None (1)'	System	30 Sep 2020 22:04:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:29', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '34016d18-7e37-41c6-a968-7d7eff3c5204' User entered '30 Sep 2020 17:04'	System	30 Sep 2020 22:04:30
	System	30 Sep 2020 22:04:30

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 6'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:24:46', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d0ccfd7-daa2-4a1f-8cd2-3426871daddf'	System	01 Oct 2020 23:25:08
User entered 'None (1)'	System	01 Oct 2020 23:25:08

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:24:51', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d0ccfd7-daa2-4a1f-8cd2-3426871daddf' User entered 'No (N)'	System	01 Oct 2020 23:25:08
	System	01 Oct 2020 23:25:08

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:24:55', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d0ccfd7-daa2-4a1f-8cd2-3426871daddf' User entered 'No (N)'	System	01 Oct 2020 23:25:08
	System	01 Oct 2020 23:25:08

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d0ccfd7-daa2-4a1f-8cd2-3426871daddf' User entered 'None (1)'	System	01 Oct 2020 23:25:08
	System	01 Oct 2020 23:25:08

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:06', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '3d0ccfd7-daa2-4a1f-8cd2-3426871daddf' User entered '01 Oct 2020 18:25'	System	01 Oct 2020 23:25:08
	System	01 Oct 2020 23:25:08

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 7'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:07:47', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bc33c921-d7b9-4e5f-8657-1ec8bba74270'	System	02 Oct 2020 22:08:10
User entered 'None (1)'	System	02 Oct 2020 22:08:10

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:07:55', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bc33c921-d7b9-4e5f-8657-1ec8bba74270' User entered 'No (N)'	System	02 Oct 2020 22:08:10
	System	02 Oct 2020 22:08:10

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bc33c921-d7b9-4e5f-8657-1ec8bba74270'	System	02 Oct 2020 22:08:10
User entered 'No (N)'	System	02 Oct 2020 22:08:10

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:04', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bc33c921-d7b9-4e5f-8657-1ec8bba74270'	System	02 Oct 2020 22:08:10
User entered 'None (1)'	System	02 Oct 2020 22:08:10

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bc33c921-d7b9-4e5f-8657-1ec8bba74270' User entered '02 Oct 2020 17:08'	System	02 Oct 2020 22:08:10
	System	02 Oct 2020 22:08:10

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 09:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 12:29'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:17', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered 'None (0)'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered 'None (0)'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered 'None (0)'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:28', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered 'None (0)'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:31', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered 'None (0)'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered 'None (0)'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:41', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered 'No (N)'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-26T16:23:44', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '987c01db-f6af-4fca-8650-eaf118d4edbe' User entered '26 Sep 2020 16:23'	System	26 Sep 2020 21:23:46
	System	26 Sep 2020 21:23:46

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '26 Sep 2020 13:24'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 2'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:09', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered 'None (0)'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:11', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered 'None (0)'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered 'None (0)'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered 'None (0)'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered 'None (0)'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered 'None (0)'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:32', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered 'No (N)'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-27T18:29:36', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd065df87-b279-4c61-a491-4fa17d15c87c' User entered '27 Sep 2020 18:29'	System	27 Sep 2020 23:29:38
	System	27 Sep 2020 23:29:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 3'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:31', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03' User entered 'None (0)'	System	28 Sep 2020 21:20:10
	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03' User entered 'None (0)'	System	28 Sep 2020 21:20:10
	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:42', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03' User entered 'None (0)'	System	28 Sep 2020 21:20:10
	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:49', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03' User entered 'None (0)'	System	28 Sep 2020 21:20:10
	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:52', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03' User entered 'None (0)'	System	28 Sep 2020 21:20:10
	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:19:56', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03' User entered 'None (0)'	System	28 Sep 2020 21:20:10
	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:20:04', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03'	System	28 Sep 2020 21:20:10
User entered 'No (N)'	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-28T16:20:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '08358baf-a6c8-4459-9918-91b35c6d9f03' User entered '28 Sep 2020 16:20'	System	28 Sep 2020 21:20:10
	System	28 Sep 2020 21:20:10

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 4'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:31', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered 'None (0)'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered 'None (0)'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:37', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered 'None (0)'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:40', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered 'None (0)'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:43', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered 'None (0)'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:46', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered 'None (0)'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:50', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered 'No (N)'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-29T17:32:54', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '02e04e97-9a1e-445a-887d-5a75135260b2' User entered '29 Sep 2020 17:32'	System	29 Sep 2020 22:32:55
	System	29 Sep 2020 22:32:55

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 5'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:33', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82' User entered 'None (0)'	System	30 Sep 2020 22:04:59
	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:36', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82' User entered 'None (0)'	System	30 Sep 2020 22:04:59
	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:39', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82' User entered 'None (0)'	System	30 Sep 2020 22:04:59
	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:42', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82' User entered 'None (0)'	System	30 Sep 2020 22:04:59
	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:44', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82' User entered 'None (0)'	System	30 Sep 2020 22:04:59
	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:47', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82' User entered 'None (0)'	System	30 Sep 2020 22:04:59
	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:51', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82'	System	30 Sep 2020 22:04:59
User entered 'No (N)'	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-09-30T17:04:54', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c6e54fd7-861f-424b-8f30-242a9f481f82' User entered '30 Sep 2020 17:04'	System	30 Sep 2020 22:04:59
	System	30 Sep 2020 22:04:59

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 6'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:12', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6'	System	01 Oct 2020 23:25:38
User entered 'None (0)'	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6'	System	01 Oct 2020 23:25:38
User entered 'None (0)'	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:19', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6' User entered 'None (0)'	System	01 Oct 2020 23:25:38
	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:22', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6' User entered 'None (0)'	System	01 Oct 2020 23:25:38
	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6'	System	01 Oct 2020 23:25:38
User entered 'None (0)'	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6'	System	01 Oct 2020 23:25:38
User entered 'None (0)'	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:32', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6'	System	01 Oct 2020 23:25:38
User entered 'No (N)'	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-01T18:25:36', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fd908ffe-fc7f-4ce0-bb22-b95e8af95cf6'	System	01 Oct 2020 23:25:38
User entered '01 Oct 2020 18:25'	System	01 Oct 2020 23:25:38

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	26 Sep 2020 14:43:24
User entered 'Day 7'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:12', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered 'None (0)'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered 'None (0)'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered 'None (0)'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:24', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered 'None (0)'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered 'None (0)'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:30', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered 'None (0)'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:35', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered 'No (N)'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-02T17:08:38', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'bb32080b-36c8-4879-bd9f-9146ba370130' User entered '02 Oct 2020 17:08'	System	02 Oct 2020 22:08:41
	System	02 Oct 2020 22:08:41

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 14:43:24

US3592238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:22:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 14:43:24

US3592238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:21:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:56:45

US3592238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:21:23
User entered '3 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 20:56:45

US3592238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:21:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 20:56:45

US3592238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:23
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:56:45

US3592238

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:31:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:56:49

US3592238

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	07 Oct 2020 20:56:49

US3592238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:21:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 20:34:18

US3592238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:21:44
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 20:34:18

US3592238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:21:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 20:34:18

US3592238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:21:44
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 20:34:18

US3592238

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:21:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 20:34:22

US3592238

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	12 Oct 2020 20:34:22

US3592238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:02:35
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Entered in EDC' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 23:36:07
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:22:09
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:02:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:36:56

US3592238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:22:09
User entered '17 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:36:56

US3592238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:22:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 16:36:56

US3592238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:22:09
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:36:56

US3592238

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:22:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:37:02

US3592238

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	20 Oct 2020 16:37:02

US3592238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:22:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:58:54

US3592238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:22:35
User entered '26 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 17:58:54

US3592238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:22:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 17:58:54

US3592238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'VISIT3'	System	11 Nov 2020 17:58:54

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered '26 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered '15:53'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '26 Oct 2020 15:53'	System	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered '98.4' F	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered '71'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'bpm'	System	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User entered '16'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'breaths/min'	System	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 10:12:34
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' answered with 'Not clinically significant per investigator' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 23:33:01
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:23:38
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:43:02
User entered '168'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:23:38
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 05:09:25
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not clinically significant per investigator' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 18:01:32
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		11 Nov 2020 18:00:20
User entered '101'	(b) (4), (b) (6)	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'mmHg'	System	11 Nov 2020 18:00:20

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47

US3592238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47

US3592238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:25:06
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:01:57

US3592238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:25:06
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:01:57

US3592238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:25:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:02:39

US3592238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:25:10
User entered '26 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 18:02:39

US3592238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:25:10
User entered '16:50'	(b) (4), (b) (6)	11 Nov 2020 18:02:39

US3592238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered '26 Oct 2020 16:50'	System	11 Nov 2020 18:02:39

US3592238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:01:54
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:25:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:02:53

US3592238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'I'	System	11 Nov 2020 18:02:53

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 64'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-29T16:13:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd27d0179-e74d-47f7-91ad-2bafd3d3a692'	System	29 Oct 2020 21:13:38
User entered 'No (N)'	System	29 Oct 2020 21:13:38

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-29T16:13:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd27d0179-e74d-47f7-91ad-2bafd3d3a692'	System	29 Oct 2020 21:13:38
User entered 'No (N)'	System	29 Oct 2020 21:13:38

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-10-29T16:13:33', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'd27d0179-e74d-47f7-91ad-2bafd3d3a692' User entered '29 Oct 2020 16:13:33'	System	29 Oct 2020 21:13:38
	System	29 Oct 2020 21:13:38

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 71'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-05T18:14:55', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c9a9a4e6-1933-46ed-bc53-68a6ea61ac59'	System	06 Nov 2020 00:15:13
User entered 'No (N)'	System	06 Nov 2020 00:15:13

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-05T18:15:04', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c9a9a4e6-1933-46ed-bc53-68a6ea61ac59'	System	06 Nov 2020 00:15:13
User entered 'No (N)'	System	06 Nov 2020 00:15:13

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-05T18:15:10', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c9a9a4e6-1933-46ed-bc53-68a6ea61ac59' User entered '05 Nov 2020 18:15:10'	System	06 Nov 2020 00:15:13
	System	06 Nov 2020 00:15:13

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered 'Day 78'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-13T02:48:06', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '382b5ffe-f6ad-4554-a606-a566efad418b' User entered 'No (N)'	System	13 Nov 2020 08:48:27
	System	13 Nov 2020 08:48:27

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-13T02:48:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '382b5ffe-f6ad-4554-a606-a566efad418b'	System	13 Nov 2020 08:48:27
User entered 'No (N)'	System	13 Nov 2020 08:48:27

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-13T02:48:23', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '382b5ffe-f6ad-4554-a606-a566efad418b' User entered '13 Nov 2020 02:48:23'	System	13 Nov 2020 08:48:27
	System	13 Nov 2020 08:48:27

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 15:27:40

US3592238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:49:47
Data entry locked.	System	29 Aug 2020 15:27:40
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 15:27:40

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-20T02:39:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '91bff5f2-9a12-4c4a-9b9f-8c1a54850ab0' User entered 'No (N)'	System	20 Nov 2020 08:40:19

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-20T02:40:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '91bff5f2-9a12-4c4a-9b9f-8c1a54850ab0' User entered 'No (N)'	System	20 Nov 2020 08:40:19

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-20T02:40:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '91bff5f2-9a12-4c4a-9b9f-8c1a54850ab0' User entered '20 Nov 2020 02:40:16'	System	20 Nov 2020 08:40:19
	System	20 Nov 2020 08:40:19

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-26T08:18:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '60cd1b51-f66f-4b8e-9ecb-a7b742399f98'	System	26 Nov 2020 14:19:09
User entered 'No (N)'	System	26 Nov 2020 14:19:09

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-26T08:19:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '60cd1b51-f66f-4b8e-9ecb-a7b742399f98'	System	26 Nov 2020 14:19:09
User entered 'No (N)'	System	26 Nov 2020 14:19:09

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-11-26T08:19:06', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '60cd1b51-f66f-4b8e-9ecb-a7b742399f98'	System	26 Nov 2020 14:19:09
User entered '26 Nov 2020 08:19:06'	System	26 Nov 2020 14:19:09

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-04T01:39:03', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2e0bd05f-27ad-41ba-89a9-725d87436fdc' User entered 'No (N)'	System	04 Dec 2020 07:39:14

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-04T01:39:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2e0bd05f-27ad-41ba-89a9-725d87436fdc' User entered 'No (N)'	System	04 Dec 2020 07:39:14

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-04T01:39:11', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2e0bd05f-27ad-41ba-89a9-725d87436fdc' User entered '04 Dec 2020 01:39:11'	System	04 Dec 2020 07:39:14
	System	04 Dec 2020 07:39:14

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-10T17:35:28', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fb36ba88-7832-407e-a169-b20fdd2a156b' User entered 'No (N)'	System	10 Dec 2020 23:35:37
	System	10 Dec 2020 23:35:37

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-10T17:35:30', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fb36ba88-7832-407e-a169-b20fdd2a156b' User entered 'No (N)'	System	10 Dec 2020 23:35:37

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-10T17:35:34', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'fb36ba88-7832-407e-a169-b20fdd2a156b' User entered '10 Dec 2020 17:35:34'	System	10 Dec 2020 23:35:37
	System	10 Dec 2020 23:35:37

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-18T16:25:42', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b590d4b2-b3ba-4b52-951a-4c1ce6e4aecc' User entered 'No (N)'	System	18 Dec 2020 22:25:58
	System	18 Dec 2020 22:25:58

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-18T16:25:47', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b590d4b2-b3ba-4b52-951a-4c1ce6e4aecc'	System	18 Dec 2020 22:25:58
User entered 'No (N)'	System	18 Dec 2020 22:25:58

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-18T16:25:54', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'b590d4b2-b3ba-4b52-951a-4c1ce6e4aecc' User entered '18 Dec 2020 16:25:54'	System	18 Dec 2020 22:25:58
	System	18 Dec 2020 22:25:58

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-24T17:42:07', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c936b514-e021-42c5-bb12-c9c75a26cc03'	System	24 Dec 2020 23:42:19
User entered 'No (N)'	System	24 Dec 2020 23:42:19

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-24T17:42:13', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c936b514-e021-42c5-bb12-c9c75a26cc03' User entered 'No (N)'	System	24 Dec 2020 23:42:19
	System	24 Dec 2020 23:42:19

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2020-12-24T17:42:16', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'c936b514-e021-42c5-bb12-c9c75a26cc03' User entered '24 Dec 2020 17:42:16'	System	24 Dec 2020 23:42:19
	System	24 Dec 2020 23:42:19

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-01T09:07:08', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '278c17a9-ef41-4d37-ad39-cc86cecc5a94' User entered 'No (N)'	System	01 Jan 2021 15:07:21
	System	01 Jan 2021 15:07:21

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-01T09:07:15', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '278c17a9-ef41-4d37-ad39-cc86cecc5a94' User entered 'No (N)'	System	01 Jan 2021 15:07:21
	System	01 Jan 2021 15:07:21

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-01T09:07:19', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '278c17a9-ef41-4d37-ad39-cc86cecc5a94' User entered '01 Jan 2021 09:07:19'	System	01 Jan 2021 15:07:21
	System	01 Jan 2021 15:07:21

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-07T16:04:52', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '50d8f7f7-5391-4739-8c79-3833c380314a' User entered 'No (N)'	System	07 Jan 2021 22:05:03

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-07T16:04:54', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '50d8f7f7-5391-4739-8c79-3833c380314a' User entered 'No (N)'	System	07 Jan 2021 22:05:03

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-07T16:04:59', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '50d8f7f7-5391-4739-8c79-3833c380314a' User entered '07 Jan 2021 16:04:59'	System	07 Jan 2021 22:05:03
	System	07 Jan 2021 22:05:03

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-15T17:49:45', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '423f5010-ff84-41f6-8a6d-2aaac357665b' User entered 'No (N)'	System	15 Jan 2021 23:49:57

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-15T17:49:50', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '423f5010-ff84-41f6-8a6d-2aaac357665b' User entered 'No (N)'	System	15 Jan 2021 23:49:57

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-15T17:49:54', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '423f5010-ff84-41f6-8a6d-2aaac357665b' User entered '15 Jan 2021 17:49:54'	System	15 Jan 2021 23:49:57
	System	15 Jan 2021 23:49:57

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-22T04:28:20', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8c2c8b93-4898-48f0-927b-3ef48d299c43' User entered 'No (N)'	System	22 Jan 2021 10:28:30

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-22T04:28:25', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8c2c8b93-4898-48f0-927b-3ef48d299c43' User entered 'No (N)'	System	22 Jan 2021 10:28:30

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-22T04:28:28', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8c2c8b93-4898-48f0-927b-3ef48d299c43' User entered '22 Jan 2021 04:28:28'	System	22 Jan 2021 10:28:30
	System	22 Jan 2021 10:28:30

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-28T19:41:43', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ff192ad7-984a-4120-b256-bd1651bbd150' User entered 'No (N)'	System	29 Jan 2021 01:41:58

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-28T19:41:50', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ff192ad7-984a-4120-b256-bd1651bbd150' User entered 'No (N)'	System	29 Jan 2021 01:41:58
	System	29 Jan 2021 01:41:58

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-01-28T19:41:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ff192ad7-984a-4120-b256-bd1651bbd150' User entered '28 Jan 2021 19:41:53'	System	29 Jan 2021 01:41:58
	System	29 Jan 2021 01:41:58

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-09T15:49:45', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8bdfc6c8-97ca-4065-acc9-65a72c547520' User entered 'No (N)'	System	09 Feb 2021 21:49:55
	System	09 Feb 2021 21:49:55

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-09T15:49:49', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8bdfc6c8-97ca-4065-acc9-65a72c547520'	System	09 Feb 2021 21:49:55
User entered 'No (N)'	System	09 Feb 2021 21:49:55

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-09T15:49:53', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '8bdfc6c8-97ca-4065-acc9-65a72c547520' User entered '09 Feb 2021 15:49:53'	System	09 Feb 2021 21:49:55
	System	09 Feb 2021 21:49:55

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-15T11:11:23', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '0f18de9f-dd1b-4878-9cb9-8a7be77cade7' User entered 'No (N)'	System	15 Feb 2021 17:16:47
	System	15 Feb 2021 17:16:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-15T11:11:27', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '0f18de9f-dd1b-4878-9cb9-8a7be77cade7'	System	15 Feb 2021 17:16:47
User entered 'No (N)'	System	15 Feb 2021 17:16:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-15T11:11:32', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '0f18de9f-dd1b-4878-9cb9-8a7be77cade7'	System	15 Feb 2021 17:16:47
User entered '15 Feb 2021 11:11:32'	System	15 Feb 2021 17:16:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-23T15:43:15-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2719ab2e-b051-43e3-9038-aacd62c82a55' User entered 'No (N)'	System	23 Feb 2021 21:43:37

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-23T15:43:22-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2719ab2e-b051-43e3-9038-aacd62c82a55' User entered 'No (N)'	System	23 Feb 2021 21:43:37

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-02-23T15:43:28-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '2719ab2e-b051-43e3-9038-aacd62c82a55'	System	23 Feb 2021 21:43:37
User entered '23 Feb 2021 21:43:28'	System	23 Feb 2021 21:43:37

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-01T16:12:55-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '342d729f-af28-4f75-90d7-bc0357704567'	System	01 Mar 2021 22:13:06
User entered 'No (N)'	System	01 Mar 2021 22:13:06

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-01T16:12:59-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '342d729f-af28-4f75-90d7-bc0357704567'	System	01 Mar 2021 22:13:06
User entered 'No (N)'	System	01 Mar 2021 22:13:06

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-01T16:13:03-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '342d729f-af28-4f75-90d7-bc0357704567'	System	01 Mar 2021 22:13:06
User entered '01 Mar 2021 16:13:03'	System	01 Mar 2021 22:13:06

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-08T15:56:14-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '93c7700c-dd04-4222-8dbc-822641e07dd9'	System	08 Mar 2021 21:56:29
User entered 'No (N)'	System	08 Mar 2021 21:56:29

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-08T15:56:19-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '93c7700c-dd04-4222-8dbc-822641e07dd9'	System	08 Mar 2021 21:56:29
User entered 'No (N)'	System	08 Mar 2021 21:56:29

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-08T15:56:25-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '93c7700c-dd04-4222-8dbc-822641e07dd9' User entered '08 Mar 2021 15:56:25'	System	08 Mar 2021 21:56:29

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-17T04:10:55-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'beb960f-45d7-431b-b714-3028f7151c10'	System	17 Mar 2021 09:11:10
User entered 'No (N)'	System	17 Mar 2021 09:11:10

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-17T04:11:01-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'beb960f-45d7-431b-b714-3028f7151c10'	System	17 Mar 2021 09:11:10
User entered 'No (N)'	System	17 Mar 2021 09:11:10

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-17T04:11:07-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'beb960f-45d7-431b-b714-3028f7151c10'	System	17 Mar 2021 09:11:10
User entered '17 Mar 2021 04:11:07'	System	17 Mar 2021 09:11:10

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-22T14:12:14-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '1585963a-e2f1-430f-8aa1-a7227f57974c' User entered 'Yes (Y)'	System	22 Mar 2021 19:12:47
	System	22 Mar 2021 19:12:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-22T14:12:19-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '1585963a-e2f1-430f-8aa1-a7227f57974c'	System	22 Mar 2021 19:12:47
User entered 'No (N)'	System	22 Mar 2021 19:12:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-22T14:12:28-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '1585963a-e2f1-430f-8aa1-a7227f57974c'	System	22 Mar 2021 19:12:47
User entered 'No (N)'	System	22 Mar 2021 19:12:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-22T14:12:38-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '1585963a-e2f1-430f-8aa1-a7227f57974c'	System	22 Mar 2021 19:12:47
User entered 'No (N)'	System	22 Mar 2021 19:12:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-22T14:12:44-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '1585963a-e2f1-430f-8aa1-a7227f57974c' User entered '22 Mar 2021 14:12:44'	System	22 Mar 2021 19:12:47
	System	22 Mar 2021 19:12:47

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-30T02:03:55-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9424279c-c6df-4955-9b77-1fac7b1c873c' User entered 'No (N)'	System	30 Mar 2021 07:04:17
	System	30 Mar 2021 07:04:17

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-30T02:04:06-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9424279c-c6df-4955-9b77-1fac7b1c873c' User entered 'No (N)'	System	30 Mar 2021 07:04:17
	System	30 Mar 2021 07:04:17

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-30T02:04:13-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9424279c-c6df-4955-9b77-1fac7b1c873c' User entered '30 Mar 2021 02:04:13'	System	30 Mar 2021 07:04:17
	System	30 Mar 2021 07:04:17

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-05T14:31:54-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9addd080-fded-4c8c-888a-142046f06773' User entered 'Yes (Y)'	System	05 Apr 2021 19:32:44

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-05T14:31:59-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9addd080-fded-4c8c-888a-142046f06773' User entered 'No (N)'	System	05 Apr 2021 19:32:44

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-05T14:32:06-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9addd080-fded-4c8c-888a-142046f06773' User entered 'No (N)'	System	05 Apr 2021 19:32:44
	System	05 Apr 2021 19:32:44

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-05T14:32:16-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9addd080-fded-4c8c-888a-142046f06773' User entered 'Yes (Y)'	System	05 Apr 2021 19:32:44

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Please 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-05T14:32:24-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9addd080-fded-4c8c-888a-142046f06773'	System	05 Apr 2021 19:32:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Apr 2021 19:32:44

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-05T14:32:29-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '9addd080-fded-4c8c-888a-142046f06773' User entered '05 Apr 2021 14:32:29'	System	05 Apr 2021 19:32:44
	System	05 Apr 2021 19:32:44

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-12T20:35:26-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'e12ddc6d-0089-4fa7-8bd3-3a6ceeba603e' User entered 'No (N)'	System	13 Apr 2021 01:38:18
	System	13 Apr 2021 01:38:18

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-12T20:35:31-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'e12ddc6d-0089-4fa7-8bd3-3a6ceeba603e' User entered 'No (N)'	System	13 Apr 2021 01:38:18

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-12T20:35:36-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'e12ddc6d-0089-4fa7-8bd3-3a6ceeba603e' User entered '12 Apr 2021 20:35:36'	System	13 Apr 2021 01:38:18
	System	13 Apr 2021 01:38:18

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-19T10:34:09-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '15f3efd5-e373-41e3-ace2-24a49d927230'	System	19 Apr 2021 15:34:23
User entered 'No (N)'	System	19 Apr 2021 15:34:23

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-19T10:34:15-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '15f3efd5-e373-41e3-ace2-24a49d927230' User entered 'No (N)'	System	19 Apr 2021 15:34:23

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-19T10:34:19-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '15f3efd5-e373-41e3-ace2-24a49d927230'	System	19 Apr 2021 15:34:23
User entered '19 Apr 2021 10:34:19'	System	19 Apr 2021 15:34:23

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-26T15:54:05-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '00e4436f-dfe8-4a44-b0f5-45b69289bdea' User entered 'No (N)'	System	26 Apr 2021 20:54:17
	System	26 Apr 2021 20:54:17

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-26T15:54:09-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '00e4436f-dfe8-4a44-b0f5-45b69289bdea' User entered 'No (N)'	System	26 Apr 2021 20:54:17

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-04-26T15:54:13-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: '00e4436f-dfe8-4a44-b0f5-45b69289bdea' User entered '26 Apr 2021 15:54:13'	System	26 Apr 2021 20:54:17
	System	26 Apr 2021 20:54:17

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-05-03T20:19:12-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ccc4856e-ec40-4f4b-ad05-d805dece251c' User entered 'No (N)'	System	04 May 2021 01:24:11

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

Have you been exposed to someone with 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 (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-05-03T20:19:21-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ccc4856e-ec40-4f4b-ad05-d805dece251c' User entered 'No (N)'	System	04 May 2021 01:24:11

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-05-03T20:19:26-05:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'ccc4856e-ec40-4f4b-ad05-d805dece251c' User entered '03 May 2021 20:19:26'	System	04 May 2021 01:24:11
	System	04 May 2021 01:24:11

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:26:43

US3592238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:22:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:26:43
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:26:43

US3592238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:22:53

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 20:27:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-01T16:13:10-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'be624a8c-d3a5-4116-9dfb-e4e8b94a7950'	System	01 Mar 2021 22:13:20
User entered 'No (N)'	System	01 Mar 2021 22:13:20

US3592238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:22:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:27:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC0C3935-E7E2-4A17-A38A-14A2A6A53E4D)', Time: '2021-03-01T16:13:17-06:00', User OID: 'PatientReportedOutcome (US3592238)', ODM File OID: 'be624a8c-d3a5-4116-9dfb-e4e8b94a7950'	System	01 Mar 2021 22:13:20
User entered '01 Mar 2021 16:13:17'	System	01 Mar 2021 22:13:20

US3592238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:07
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:26:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:09:50

US3592238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:07
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	14 Jan 2021 15:35:31
User closed query 'Please confirm/correct, Date of contact is inconsistent with source where source reflects date to be 21 Nov 2020.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 15:35:29
Query 'Please confirm/correct, Date of contact is inconsistent with source where source reflects date to be 21 Nov 2020.' answered with 'data corrected' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 23:34:14
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Dec 2020 23:33:56
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	29 Dec 2020 23:33:56
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 23:33:56
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 23:33:56
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:26:30
User opened query 'Please confirm/correct, Date of contact is inconsistent with source where source reflects date to be 21 Nov 2020.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 18:26:20
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Nov 2020 18:09:50
User entered '10 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 18:09:50

US3592238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:07
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:26:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 18:09:50

US3592238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:26:30
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:09:50

US3592238

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:07
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:26:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:10:27

US3592238

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:32:47
User entered 'l'	System	11 Nov 2020 18:10:27

US3592238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (U) (4), (U) (6)	29 Dec 2020 23:30:10

US3592238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:30:10

US3592238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:30:10

US3592238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:30:10

US3592238

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:30:16

US3592238

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User entered 'l'	System	29 Dec 2020 23:30:16

US3592238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:20:47

US3592238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:20:47

US3592238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:20:47

US3592238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:20:47

US3592238

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:21:03

US3592238

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User entered 'l'	System	28 Jan 2021 18:21:03

US3592238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Mar 2021 14:11:00

US3592238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '23 Feb 2021'	(b) (4) (u) (4), (b) (6)	05 Mar 2021 14:11:00

US3592238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	05 Mar 2021 14:11:00

US3592238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:22:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 14:11:00

US3592238

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Mar 2021 14:17:03

US3592238

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:11:07
User entered 'l'	System	05 Mar 2021 14:17:03

US3592238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:44:07

US3592238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:44:07

US3592238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[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 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:44:07

US3592238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered 'VISIT4'	System	16 Mar 2021 14:44:07

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '15 Mar 2021'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '16:03'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered '15 Mar 2021 16:03'	System	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '37.0' C	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Oral (Oral)'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered empty.	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '86'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered 'bpm'	System	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '16'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered 'breaths/min'	System	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '123'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered 'mmHg'	System	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '84'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered 'mmHg'	System	06 Apr 2021 14:14:02

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22

US3592238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:22:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22

US3592238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:44:36

US3592238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:22:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:44:36

US3592238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:45:17

US3592238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is reported under Visit 04 with date 16MAR2021 in PPD Central lab. Please review and confirm the CORRECT DATE in query response for this Visit. Else Clarify, Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 09:34:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is reported under Visit 04 with date 16MAR2021 in PPD Central lab. Please review and confirm the CORRECT DATE in query response for this Visit. Else Clarify, Thank you ' answered with 'Confirming this date for this sample. Collection date entered incorrectly on req, will reconcile with PPD Central Lab' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 15:48:04
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is reported under Visit 04 with date 16MAR2021 in PPD Central lab. Please review and confirm the CORRECT DATE in query response for this Visit. Else Clarify, Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 07:06:01
User entered '15 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 14:45:17

US3592238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '16:20'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:45:17

US3592238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered '15 Mar 2021 16:20'	System	16 Mar 2021 14:45:17

US3592238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:45:29

US3592238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:22:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:22
User entered 'l'	System	16 Mar 2021 14:45:29

US3592238

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

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:19:41

US3592238

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

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '8 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:23:22
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 20:19:41

US3592238

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

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[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 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:19:41

US3592238

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

Form: Visit Date

Generated On: 10 Jun 2021 08:22:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 20:19:41

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[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 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:27:08

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:27:08

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User entered empty.	System	09 Feb 2021 20:21:45

US3592238

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

Form: Unblinding

Generated On: 10 Jun 2021 08:22:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User entered empty.	System	09 Feb 2021 20:21:45

US3592238

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:49

US3592238

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	09 Feb 2021 20:23:22
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	09 Feb 2021 20:23:22
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:22:49
User entered '8 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 20:22:49

US3592238

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '15:40'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:49

US3592238

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User entered '8 Feb 2021 15:40'	System	09 Feb 2021 20:22:49

US3592238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:22:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:53

US3592238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:22:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:53

US3592238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:22:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '15:44'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:23:53

US3592238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:17
User entered '8 Feb 2021 15:44'	System	09 Feb 2021 20:23:53

US3592238

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:22:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:53
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:26:13
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 20:26:13
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:06:18
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 17:02:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 19:30:40
User entered 'USA-US103-2021-mRNA-1273-P301000008'	System	07 Apr 2021 19:30:26
User entered 'New'	(b) (4), (b) (6)	07 Apr 2021 19:30:26

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The medication Lantus Solostar was given for type 1 diabetes. Was the subject diagnosed with type 1 diabetes? If so, please consider updating the event term to the underlying etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 00:41:26
Query 'PV Query: The medication Lantus Solostar was given for type 1 diabetes. Was the subject diagnosed with type 1 diabetes? If so, please consider updating the event term to the underlying etiology of the event.' answered with 'indication updated since AE term was updated and updated to match AE term ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:06:33
User opened query 'PV Query: The medication Lantus Solostar was given for type 1 diabetes. Was the subject diagnosed with type 1 diabetes? If so, please consider updating the event term to the underlying etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:12:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 20:15:53
Data point term sent to Coder	System	15 Apr 2021 20:14:59
Coding entries removed.	(b) (4), (b) (6)	15 Apr 2021 20:14:41
User entered 'hyperglycemia' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 20:14:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:34:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 20:34:18
Data point term sent to Coder	System	06 Apr 2021 20:33:41
User entered 'Diabetes Mellitus Type II'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Diandra Henriques (b) (4)	21 Apr 2021 18:58:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Mar 2021' reason for change: New Information	Diandra Henriques (b) (4)	21 Apr 2021 18:58:31
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:33:14
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 15:29:39
User entered empty.	System	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed 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).	(b) (4), (b) (6)	08 Apr 2021 02:50:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 20:33:33
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.' answered with 'unknown until records are received ' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 20:33:14
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	06 Apr 2021 20:32:46
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'l'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 16:23:25
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Outcome of SAE updated, will add DMII (sequelae) to AE form.' (Site from Safety).	Diandra Henriques (b) (4)	21 Apr 2021 19:00:38
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	21 Apr 2021 18:58:31
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Diandra Henriques (b) (4)	21 Apr 2021 18:58:31
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 15:31:31
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	06 Apr 2021 20:32:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered 'Subject reported during TC with research assistant on 05-Apr-2021 at 1503 that on 23MAR2021 he was experiencing blurred vision and drove himself to the emergency room at Wesley Medical Center.'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The event was reported as resolved with sequelae. Please confirm sequelae of DMII (per query response) and add to SAE form.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:34:27
User opened query 'PV Query: Did the subject have a medical history of type 1 diabetes? Was the SAE considered a worsening of the subject's medical history of type 1 diabetes?' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:12:13
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)	22 Apr 2021 13:12:00
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:11:47
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:11:23

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'HE WAS FOUND TO HAVE A BLOOD GLUCOSE LEVEL OF 960 AND WAS ADMITTED TO THE HOSPITAL. PER HIS REPORT HE WAS DISCHARGED AFTER 4 DAYS ON INSULIN (LANTUS) AND DIAGNOSED WITH DIABETES. WILL HAVE SUBJECT SIGN RECORD RELEASE FOR MORE INFORMATION FOLLOW UP REPORT TO BE SUBMITTED WHEN RECORDS RECEIVED. 4/15/2021 FU#1 MEDICAL RECORDS RELEASE SENT BUT RECORDS PENDING. SAE TERM CHANGED FROM DIABETES TO HYPERGLYCEMIA 4/21/21 FU#2 - UPDATED OUTCOME AND END DATE. RECORDS STILL PENDING.' reason for change: New Information	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 18:59:49
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 15:33:50
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)	16 Apr 2021 15:33:10

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'HE WAS FOUND TO HAVE A BLOOD GLUCOSE LEVEL OF 960 AND WAS ADMITTED TO THE HOSPITAL. PER HIS REPORT HE WAS DISCHARGED AFTER 4 DAYS ON INSULIN (LANTUS) AND DIAGNOSED WITH DIABETES. WILL HAVE SUBJECT SIGN RECORD RELEASE FOR MORE INFORMATION FOLLOW UP REPORT TO BE SUBMITTED WHEN RECORDS RECEIVED. 4/15/2021 FU#1 Medical records release sent but records pending. SAE term changed from diabetes to hyperglycemia' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 20:14:41
User entered 'He was found to have a blood glucose level of 960 and was admitted to the hospital. Per his report he was discharged after 4 days on insulin (lantus) and diagnosed with diabetes. Will have subject sign record release for more information follow up report to be submitted when records received.'	(b) (4), (b) (6)	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:22:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 20:32:46

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 20:03:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 20:03:15
Data point term sent to Coder	System	21 Apr 2021 19:21:40
User entered 'DIABETES TYPE 2'	Diandra Henriques (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Mar 2021'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Diandra Henriques (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Diandra Henriques (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

None

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'l'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 19:21:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Apr 2021 19:21:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Diandra Henriques (b) (4)	21 Apr 2021 19:21:13
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 19:20:56
User entered empty.	Diandra Henriques (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 19:20:56

US3592238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:22:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Apr 2021 19:20:56

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:53
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User closed query 'please enter con-med, Lantus Solostar, that correlates with SAE that occurred on 23-Mar-2021' (Site from CRA).	(b) (4) (U) (4), (U) (6)	19 Apr 2021 14:14:52
Query 'please enter con-med, Lantus Solostar, that correlates with SAE that occurred on 23-Mar-2021' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:00:48
User opened query 'please enter con-med, Lantus Solostar, that correlates with SAE that occurred on 23-Mar-2021' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:39:12
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:06:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:33:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:35:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:35:39
Data point term sent to Coder User entered 'Norvasc'	System (b) (4), (b) (6)	29 Aug 2020 18:34:56 29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Hypertension'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '5'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 18:34:33

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN, PRODUCTSYNONYM: ZOCOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:36:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:36:39
Data point term sent to Coder User entered 'Zocor'	System (b) (4), (b) (6)	29 Aug 2020 18:35:59 29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '40'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 18:35:10

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL SODIUM, PRODUCTSYNONYM: ALOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:36:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:36:39
Data point term sent to Coder User entered 'Aloprim'	System (b) (4), (b) (6)	29 Aug 2020 18:35:59 29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Gout'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '300'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 18:35:44

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:02:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:02:51
Data point term sent to Coder	System	29 Aug 2020 18:38:03
User entered 'Xarlotto'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#4) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:22:43
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#4) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'corrected ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 20:57:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 20:57:30
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#4) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:32:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'History of Deep Vein Thrombosis'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '20'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'UN UNK 2006'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 18:37:20

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: OLMESARTAN MEDOXOMIL, PRODUCTSYNONYM: BENICAR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:39:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:39:41
Data point term sent to Coder User entered 'Benicar'	System (b) (4), (b) (6)	29 Aug 2020 18:39:10 29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Hypertension'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User closed query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:09:57
Query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 20:58:19
User entered '40/12.5' reason for change: New Information	(b) (4), (b) (6)	07 Oct 2020 20:58:14
User opened query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:31:47
User entered 'I'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 20:58:14
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 18:38:48

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:36:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 06:36:52
Data point term sent to Coder	System	29 Aug 2020 18:44:27
User entered 'Toprol X'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Hypertension'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '100'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'UN UNK 2000'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 18:43:29

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN, PRODUCTSYNONYM: GLUCOPHAGE [METFORMIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:56:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 05:56:46
Data point term sent to Coder	System	29 Aug 2020 18:44:28
User entered 'Glucophage'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Prediabetic'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '500'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'twice daily (BID)'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'UN UNK 2017'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 18:44:11

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 23:39:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 23:39:22
Data point term sent to Coder	System	29 Dec 2020 23:38:18
Coding entries removed.	(b) (4), (b) (6)	29 Dec 2020 23:37:24
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 18:14:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 18:14:35
Data point term sent to Coder	System	11 Nov 2020 18:13:34
User entered 'influenza vaccine'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered '0.5'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'mL (mL)'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 07:42:12
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 23:37:44
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 23:37:24
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 23:37:24
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:23:44
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:37:24
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 23:37:24
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered '10 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:37:24
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 23:37:24
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered '10 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:29:25
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User entered empty.	System	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User entered empty.	System	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:11:52
User entered empty.	System	11 Nov 2020 18:13:27

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 05:04:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 05:04:29
Data point term sent to Coder	System	29 Apr 2021 21:06:22
Coding entries removed.	(b) (4), (b) (6)	29 Apr 2021 21:05:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:01:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:01:51
Data point term sent to Coder	System	08 Apr 2021 21:59:10
User entered 'Lantus Solostar'	(b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'No (N)'	(b) (4) (U) (4), (U) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:11
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 21:05:28
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 21:05:28
User entered 'HYPERGLYCEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 21:05:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'Type I diabetes'	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered '2'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'units'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered empty.	(b) (4) (U) (4), (U) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:16:20
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:22:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 21:58:55

US3592238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:22:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:56:25
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Oct 2020 21:06:27
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 17:02:40

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:01
User entered 'USA-US103-2021-MRNA-1273-P301000008'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Terry'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Poling'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '1709 S Rock Rd'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Wichita'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'KS'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '67207'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 13:49:16
User entered 'US'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 16:39:59
User entered '2'	System	16 Apr 2021 13:49:47
User entered '1'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:01
User entered 'USA-US103-2021-MRNA-1273-P301000008'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Terry'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Poling'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '1709 S Rock Rd'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Wichita'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'KS'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '67207'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 13:49:16
User entered 'US'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 16:39:59
User entered '2'	System	16 Apr 2021 13:49:47
User entered '1'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:22:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '07/Apr/2021 15:31'	(b) (4) System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:22:53

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 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 13:49:16
User entered 'I'	(D) (4), (D) (6)	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:01
User entered 'USA-US103-2021-MRNA-1273-P301000008'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Terry'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Poling'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '1709 S Rock Rd'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Wichita'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'KS'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '67207'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 13:49:16
User entered 'US'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 16:39:59
User entered '2'	System	16 Apr 2021 13:49:47
User entered '1'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:22:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '16/Apr/2021 09:49'	(b) (4) System	16 Apr 2021 13:49:47

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:22:53

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 09:42:25
User entered 'I'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 13:49:47

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:01
User entered 'USA-US103-2021-MRNA-1273-P301000008'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Yes (Y)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'No (N)'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Terry'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Poling'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '1709 S Rock Rd'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'Wichita'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered 'KS'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	07 Apr 2021 19:31:05
User entered '67207'	System	07 Apr 2021 19:30:26

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 13:49:16
User entered 'US'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:22:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 16:39:59
User entered '2'	System	16 Apr 2021 13:49:47
User entered '1'	System	07 Apr 2021 19:31:24

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:22:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:42:25
User entered '22/Apr/2021 12:39'	(b) (4) System	22 Apr 2021 16:39:59

US3592238

Folder: SAE USA-US103-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:22:53

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 09:42:25
User entered 'I'	(b) (4) (D) (4), (D) (6)	22 Apr 2021 16:39:59